COA 43252-8-II

No. 86224-9

SUPREME COURT
OF THE STATE OF WASHINGTON

PROTECT THE PENINSULA'S FUTURE, CLALLAM COUNTY CITIZENS FOR SAFE DRINKING WATER, and ELOISE KAILIN

Appellants,

v.

CITY OF PORT ANGELES and CITY OF FORKS

Respondents,

BRIEF OF RESPONDENTS

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1. INTRODUCTION

Respondents City of Port Angeles and City of Forks ("Cities") own and operate public drinking water utilities. Under comprehensive regulation by the Washington Department of Health and Board of Health, the Cities add fluoride to their public drinking water. As recognized last year by the Washington Supreme Court, both state and federal law expressly allow, and strictly regulate, fluoridation of the Cities' drinking water. *City of Port Angeles v. Our Water–Our Choice*, 170 Wn.2d 1, 259 P.3d 598 (2010); WAC 246-290-490. Petitioners' attack on these programs is meritless, and the Court should award the Cities costs and attorneys' fees in this matter. Any other result tolerates the abuse of the judicial system by parties who use the courts for political, not legal, purposes

2. ASSIGNMENTS OF ERROR AND ISSUES PERTAINING TO ASSIGNMENTS OF ERROR

2.1 Respondents' Assignments of Error.

2.1.1 The trial court committed error when it denied the Cities' request for costs and reasonable attorneys' fees under RCW 4.84.185.

2.1.2 The trial court committed error when it denied the Cities request for costs and reasonable attorneys fees under CR 11.

2.2 Issues Pertaining to Respondents' Assignments of Error.

2.2.1 The standard for an award of costs and attorneys' fees under RCW 4.84.185 is whether the action is frivolous and advanced without reasonable cause. Did the trail court err in failing to apply that standard when it denied the Cities' request for costs and attorneys' fees under RCW 4.84.185? The answer is Yes.

2.2.2 Where there are no facts or law to support a claim that the Cities' fluoridated drinking water and bulk fluoridation additives are "legend drugs" under the controlling definitions of the Washington Board of Pharmacy, is Petitioners' Complaint, which seeks to have the trial court seize the Cities' fluoridated drinking water system as a "legend drug," advanced without reasonable cause? The answer is Yes.

2.2.3 The standard for an award of costs and attorneys' fees under CR 11 is whether Petitioners' Complaint is well grounded in fact **or** warranted by existing law or a good faith argument for the extension or modification of existing law. Did the trial court err in failing to apply that correct standard when it denied the Cities' request for costs and attorneys' fees under CR 11? The answer is Yes.

2.2.4 Where the facts, easily discovered by any reasonable inquiry, conclusively show that the Cities' fluoridated drinking water and water additives do not meet the controlling Board of Pharmacy definition of "legend drug" under Washington law, is Petitioners' Complaint, which

seeks to have the trial court seize the Cities' fluoridated drinking water system as a "legend drug," well grounded in fact? The answer is No.

2.3 Response to Petitioners' Assignments of Error and Issues Pertaining to Petitioners' Assignments of Error.

The assignments of error promulgated by Petitioners are intentionally argumentative for political purposes. The issues presented by the trial court's dismissal of their Complaint are actually quite simple and should be formulated as follows:

2.3.1 Fluoridated drinking water and drinking water additives are not regulated by the FDA and are not listed in the 2009 Drug Topics Red Book, and therefore do not meet the Board of Pharmacy's controlling definition of "legend drug" under Washington law. Did the trial court correctly dismiss Petitioners' Complaint, which requested the trial court to seize the fluoridated public drinking water furnished by the Cities and the bulk fluoride additives used by the Cities (as approved and regulated by the Washington Department of Health) as illegally manufactured and distributed "legend drugs" under RCW 69.41.060? The answer is Yes.

2.3.2 The Board of Pharmacy's controlling regulations unambiguously define a "legend drug;" every court in the United States to consider the question (including the Washington Supreme Court) has determined fluoridated drinking water is not a drug; and the question of

what substances to regulate as a drug is within the primary jurisdiction of the FDA and Washington Board of Pharmacy. Did the trial court correctly deny Petitioners' motion to amend the Complaint to add a declaratory judgment action regarding whether fluoridated drinking water is a drug? The answer is Yes.

2.3.3 The Washington Supreme Court held in the *City of Port Angeles* case that fluoride is a permitted additive to public drinking water. Is that Supreme Court decision dispositive of the issues raised by Petitioners in their Complaint? The answer is Yes.

2.3.4 Petitioners failed to challenge Board of Health and Department of Health regulations regarding drinking water fluoridation and did not raise any constitutional claims below. May Petitioners challenge those regulations in this appeal and argue that those regulations violate the Supremacy Clause of the U. S. Constitution. The answer is No.

3. STATEMENT OF CASE

3.1 Prior Actions.

This is the third lawsuit challenging fluoridation of the City of Port Angeles drinking water system. In this lawsuit, the City of Forks has been sued as well.

The first lawsuit involved the same plaintiffs and same attorney and challenged Port Angeles' environmental review of its decision to

fluoridate its public drinking water.[1] Division Two of the Court of Appeals upheld the trial court's dismissal, and held that Port Angeles' fluoridation program was an action **under a program of the Washington Department of Health**.[2] The Court also found that the Port Angeles' fluoridation program was subject to the approval and continuing oversight of the Department of Health.[3]

The second lawsuit was brought by related plaintiffs and by the same attorney, and advocated for local initiatives that would effectively overturn Port Angeles' decision to adopt a water fluoridation program.[4] The Washington Supreme Court (and the Court of Appeals and trial court) invalidated the initiatives. The Supreme Court made a number of directly applicable holdings:

- The Department of Health regulations permit public water systems (such as the Cities' systems) to adopt water fluoridation programs.[5]

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[1] *Clallam County Citizens for Safe Drinking Water v. City of Port Angeles*, 137 Wn. App. 214, 151 P.3d 1079 (2007).
[2] *Clallam County Citizens* at 220.
[3] *Id.*
[4] *City of Port Angeles v. Out Water—Our Choice*, 170 Wn.2d 1, 259 P.3d 598 (2010).
[5] *City of Port Angeles*, 170 Wn.2d at 12; WAC 246-290-460.

- Public drinking water systems are extensively regulated by both the United States and the Washington State governments.[6]
- On the federal level, the EPA regulates public drinking water systems and additives; and the FDA does not regulate public drinking water systems or additives to public drinking water.[7]
- The United States Safe Drinking Water Act regulates all public drinking water systems in the United States and allows for greater state regulation.[8]
- The Washington State Legislature has vested the Department of Health and Board of Health with the power and duty to regulate the health and safety of drinking water.[9]
- The Department of Health and Board of Health have responded with detailed regulations governing public water systems at Ch. 246-290 WAC.[10]
- Those regulations include a specific regulation of fluoridation at WAC 246-290-460.[11]

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[6] *City of Port Angeles,* 170 Wn.2d at 4.
[7] *City of Port Angeles,* 170 Wn.2d at 6 (f.n. 1); *citing* Memorandum of Understanding between FDA and EPA regarding EPA's exclusive control over public drinking water (44 FR 42775).
[8] *City of Port Angeles*, 170 Wn.2d at 8.
[9] *City of Port Angeles*, 170 Wn.2d at 8; RCW 43.20.050(2)(a).
[10] *City of Port Angeles*, 170 Wn.2d at 9.

- Under the Safe Drinking Water Act and the Washington regulations, approximately 40 chemicals may be added to public water supplies, and "**[f]luoride is one of the permitted chemicals.**"[12]

3.2 The Present Action.

The present lawsuit attempts to characterize the Cities' public drinking water and chemical fluoridation additives as "legend drugs," which are drugs that may only be dispensed by prescription. Prescription drugs are regulated by the Washington Board of Pharmacy and Ch. 69.41 RCW. The Complaint asked the trial court to issue a warrant for search and seizure of the alleged "legend drugs" pursuant to RCW 69.41.060. This would allow seizure all of the Cities' public drinking water and fluoridation additives, effectively closing down the Cities' drinking water fluoridation programs that have been approved and regulated by the Washington Department of Health.

The Cities moved to dismiss Petitioners' Complaint for failure to state a claim or for judgment on the pleadings. The trial court applied clear Washington Board of Pharmacy regulations that a substance cannot be a "legend drug" under Washington law unless it is both designated as a

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[11] *Id.*

prescription drug (a legend drug) by the FDA under federal law and listed as such in the 2009 edition of the *Drug Topics Red Book.*[13] The trial court correctly found that neither part of that definition from WAC 246-883-020 was met. First, the FDA does not regulate drinking water or additives to public drinking water, much less require a prescription for the use of drinking water additives. Second, fluoridated drinking water and the bulk fluoride additives used by the Cities' are not listed in the 2009 edition of the *Drug Topics Red Book.*

In an attempt to avoid dismissal, Petitioners filed a motion to amend their Complaint.[14] The trial court dismissed Petitioners' motion as futile.[15]

4. SUMMARY OF ARGUMENT

4.1 The Trial Court Properly Dismissed Petitioners' Complaint.

The Court should uphold the trial court dismissal of Petitioners' Complaint for failure to state a claim.[16] The Complaint alleges that the Cities' fluoridated drinking water and fluoridation additives are "legend

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[12] *Id.* (emphasis added).
[13] Clerk's Papers ("CP") at 7 – 11 (Order Granting Defendant Cities' Motion To Dismiss). A copy is attached at Appendix A.
[14] CP at 200 – 204.
[15] CP at 12 – 13. A copy is attached at Appendix B.
[16] CP at 7 – 11.

drugs" – drugs requiring a prescription.[17] The trial court correctly concluded that there were no facts Petitioners could prove to prevail on that claim. Under controlling Washington Board of Pharmacy regulations, a "legend drug" must meet two requirements: (1) the U. S. Food and Drug Administration ("FDA") must classify the substance as a legend drug under federal law, and (2) the drug must be listed in the 2009 edition of the *Drug Topics Red Book.*[18] With respect to the first requirement, the FDA does not regulate public drinking water systems or drinking water additives. The FDA itself has given repeated, public notices that the U. S. Environmental Protection Agency ("EPA") has exclusive jurisdiction over drinking water and additives, and the Washington Supreme Court has expressly agreed.[19] With respect to the second requirement, Petitioners' Complaint admits that the additives used in the Cities' drinking water are not listed in the 2009 *Drug Topics Red Book.*[20] And as shown in the pages of the *Drug Topics Red Book* attached to the Complaint, neither

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[17] If granted, Petitioners' Complaint would effectively end drinking water fluoridation, which is widely practiced and accepted in the state of Washington. The Department of Health website shows at least 52 public drinking water systems provide fluoridated drinking water, and another 119 systems receive and distribute only fluoridated water through interties. http://www.doh.wa.gov/ehp/dw/fluoride.htm.

[18] WAC 246-883-020.

[19] 44 FR 42775 – 42778 (Appendix C); 63 FR 54532 at 54536 – 37 (Appendix F); *City of Port Angeles*, 170 Wn.2d at 6 (f.n. 1).

fluoridated public drinking water nor the bulk additives used by the Cities (and expressly approved by the Department of Health) are listed.[21] Because neither of the two mandatory requirements to be a "legend drug" under Washington law can possibly be met, the Court should uphold the trial court's dismissal.

4.2 The Trial Court Properly Denied Petitioners' Motion to Amend.

The Court should also uphold the trial court decision denying Petitioners' motion to amend their Complaint.[22] The amendment sought to add a claim for declaratory judgment as to whether the Cities' fluoridated public drinking water and additives were "drugs." Petitioners' sole rationale for the proposed amendment was that the court would need to determine whether fluoridated drinking water was a "drug" before it could determine it was a "legend drug." The trial court properly denied Petitioners' motion as futile. The trial court was correct for three independent reasons. First, the Board of Pharmacy's definition of "legend drug" is unambiguous, and does not require an initial inquiry as to whether a substance is a "drug." WAC 246-883-020. Second, every court to address the issue, including the Washington Supreme Court, has held that

[20] Complaint at ¶6, ¶10; CP at 259 – 260.
[21] CP at 35 - 44

fluoridated drinking water is not a drug. *E.g., Kaul v. Chehalis*, 45 Wn.2d 616, 625, 277 P.2d 352 (1955) (city providing fluoridated drinking water "is not engaged in selling drugs"). Third, the question of whether fluoridated public drinking water should be regulated as a drug is within the primary jurisdiction of the FDA and the Washington Board of Pharmacy. The trial court properly rejected Petitioners' effort as a futile claim.

4.3 This Court Should Overturn the Trial Court's Denial of the Cities' Request for Costs and Reasonable Attorneys' Fees.

Under both RCW 4.84.185 and CR 11, the courts must discourage frivolous claims. The trial court denied the Cities' requested costs and fees because the judge concluded that Petitioners were arguing for a good faith change in the law.[23] The trial court applied the incorrect legal standard to the Cities' request. Under RCW 4.84.185, the correct standard is whether the action was "frivolous and advanced without reasonable cause" – not whether Petitioners were arguing for a good faith change in the law. Under CR 11, the correct standard is whether the complaint is "well grounded in fact" or is warranted by existing law or a good faith argument for a extension or modification of the law.

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[22] CP at 12 – 13. *See* Appendix B.
[23] Verbatim Report of Proceedings ("VRP") at 40, lines 2 – 5.

In this case, the Complaint was neither advanced with reasonable cause nor well grounded in fact. Petitioners knew that the FDA did not regulate public drinking water or classify it as a legend drug, which was reiterated in last year's *City of Port Angeles* decision from the Supreme Court.[24] Petitioners knew that neither drinking water nor the drinking water additives used by the Cities were listed in the *2009 Drug Topics Red Book.* Moreover, the Washington Supreme Court had only recently held that fluoride "is one of the permitted chemicals" in drinking water.[25] Because of those incontrovertible facts, neither part of the Board of Pharmacy's definition of "legend drug" could possibly be met, and Petitioners' Complaint was wholly without merit. Therefore, this Court should overturn the trial court's denial of the Cities' request for costs and reasonable attorneys' fees, and this Court should also award the Cities their costs and reasonable attorneys' fees on appeal under RAP 18.9(a) for Petitioners' frivolous appeal of the trial court dismissal of their Complaint.

Petitioners may honestly believe that drinking water fluoridation *should* be regulated differently. Rather than address their concerns to the Legislature or to the agencies with authority over legend drugs (the FDA and the Washington Board of Pharmacy), Petitioners have instituted this

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[24] *City of Port Angeles*, 170 Wn.2d at 6 (f.n. 1).

nuisance lawsuit against the Cities, which have long provided fluoridated public drinking water under programs approved by the Washington Department of Health. This Court should put a stop to Petitioners' frivolous conduct, which burdens both the Cities' utility ratepayers and the courts.

4.4 Petitioner' Constitutional Claims Were Not Presented Below and Should Not Be Considered On Appeal.

Petitioners assert, with no citation to authority, that certain Board of Health and Department of Health regulations violate the Supremacy Clause of the U. S. Constitution, supposedly because FDA is required to regulate drinking water as a drug. These arguments were not raised below, were not pleaded in Petitioners' Complaint, and should not be considered by this Court. RAP 2.5(a).

Petitioners' constitutional claims are also plainly incorrect. The regulations cited by Petitioners do not require fluoridation, they merely regulate it when a fluoridation program is provided. Moreover, the FDA does not regulate public drinking water or drinking water additives.[26]

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[25] *City of Port Angeles*, 170 Wn.2d at 9.
[26] 44 FR 42775 – 42778 (attached at Appendix C); 63 FR 54532 at 54536 – 37 (attached at Appendix F).

5. ARGUMENT

5.1 The Cities' Public Drinking Water and Fluoridation Additives Are Not "Legend Drugs" Under Controlling Washington Law.

5.1.1 Standard of Review for Motions to Dismiss.

Dismissal of Petitioners' Complaint was proper under either CR 12(b)(6) or CR 12(c). Under either rule, the court may dismiss the Complaint where the facts will not support the relief requested. *Dave Robbins Construction Co. v. First American Title Co.*, 158 Wn. App. 895, 896, 249 P.3d 625 (2010). Dismissal is particularly appropriate when the dispositive issue before the Court is an issue of legal interpretation. *Dave Robbins*, 158 Wn. App. 895 (dismissal granted where issue was whether title commitment was required to disclose existence of historic district); *Ottgen v. Clover Park Tech. College*, 84 Wn. Ap. 214, 928 P.2d 1119 (1996) (dismissal granted where issue was whether technical college was subject to suit under the Consumer Protection Act).

Similarly in this case, the facts are incontrovertible – the FDA does not regulate drinking water or additives to drinking water (as previously found by the Supreme Court), and the Cities' bulk additives are not listed in the *Drug Topics Red Book.* Under those incontrovertible facts, the Cities' fluoridated drinking water and the fluoridation additives are not "legend drugs" as defined of the Washington Board of Pharmacy.

5.1.2 Under Washington Law, Drinking Water and the Cities' Fluoridation Additives Are Legend Drugs Only If the FDA Has Designated Them a Legend Drug Under Federal Law and They Are Listed in the 2009 Drug Topics Red Book.

Petitioners' Complaint was brought under Ch. 69.41 RCW, governing drugs requiring a prescription ("legend drugs"). Legend drugs are defined as follows:

> "Legend drugs" means any drugs which are required by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practicioners only.

RCW 69.41.010(12). The Washington Board of Pharmacy is empowered to make regulations to enforce Ch. 69.41 RCW. RCW 69.41.075. The Board of Pharmacy defines "legend drugs" for purposes of Ch. 69.41 RCW as only those drugs that meet two specific requirements:

> For the purposes of chapter 69.41 RCW, legend drugs are drugs which have been **designated as legend drugs under federal law and are listed as such in the 2009 edition of the Drug Topics Red Book.**

WAC 246-883-020(2) (emphasis supplied). Both requirements must be met in order for a substance to be a legend drug under Washington law. Neither of those requirements can possibly be met in this case, as Petitioners well knew.

5.1.3 The FDA Has Not Designated Public Drinking Water or Bulk Fluoridation Additives as Legend Drugs Under Federal Law.

The Federal Food, Drug and Cosmetics Act (the "FFDCA") is the primary federal law regulating the manufacture, use and sale of drugs; . *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 665-666 (1990). Under the FFDCA, the FDA is required to approve all prescription drugs on the U.S. market. *Ironworkers Local Union 68 v. AstraZeneca*, 634 F.3d 1352, 1355 f.n. 3 (2011); *see* 21 U.S.C. § 355(a).

The FFDCA is codified as amended at 21 USC § 301 *et seq*. No section of the FFDCA regulates public drinking water systems. The FDA has passed extensive regulations implementing that the FFDCA. 21 C.F.R. Parts 1 through 1040. None of those regulations regulate public drinking water systems.

In 1974, Congress passed the United States Safe Drinking Water Act (the "SDWA"). Pub.L. No. 95-523; codified as amended at 42 U.S.C. § 300f *et seq*. In the SDWA, Congress authorized the EPA (not the FDA) to regulate all public drinking water systems in the country. 42 U.S.C.§ 300g-1. Pursuant to Congress' direction, the EPA has published detailed drinking water standards for all public water systems in the country. 40 C.F.R. Part 141, Subpart O, App. A; 40 C.F.R. Part 143.

Because of Congress' grant of authority to the EPA in the SDWA, in 1979 the FDA and the EPA entered into a Memorandum of Understanding (the "MOU") regarding their respective jurisdiction over additives to public drinking water and drinking water additives. 44 FR 42775 – 44778 (copy attached at Appendix C); *see City of Port Angeles*, 170 Wn.2d at 6, f.n. 1. In the MOU, the EPA and FDA agreed that:

- Prior to passage of the SDWA, the FDA had regulated public drinking water as a food under Section 201(f) of the FFDCA. 44 FR 42775.[27]
- "The express intent of the [Safe Drinking Water] Act was to give EPA exclusive control over public drinking water supplies." 44 FR 42776.
- The Safe Drinking Water Act's passage in 1974 implicitly repealed FDA's jurisdiction over drinking water. 44 FR 42776.

[27] Petitioners claim that FDA only gave up its "food" jurisdiction over drinking water due to the SDWA, not its "drug" jurisdiction. Nothing could be further from correct. The 1979 MOU and later MOUs state clearly that EPA has exclusive jurisdiction over drinking water and drinking water additives. In fact, the FDA has never regulated public drinking water as a drug, even before the passage of the SDWA. *See* former 21 C.F.R. 250.203, which was an FDA regulation in place prior to the SDWA ("Public water supplies do not ordinarily come under the provisions of the Federal Food, Drug and Cosmetic Act.").

- "Under the agreement, **the EPA now retains exclusive jurisdiction over drinking water served by served by public water supplies, including any additives in such water.**" 44 FR 42776 (emphasis added).

The 1979 MOU is still in full force and effect. Every case to consider the question agrees that the FDA does not regulate drinking water or treatment additives. *E.g., Coshow v. City of Escondido*, 132 Cal. App. 4th 687, 713, 34 Cal. Rptr. 3d 19, 34 (2005) ("The FDA's authority over food, drugs and cosmetics, including its regulation of fluoride in various products, does not extend to public supplies of drinking water.").

Petitioners claim in their Opening Brief that the MOU has been terminated by a notice given by EPA in 1988. Opening Brief at 23 – 24. That claim is disingenuous and false. This Court should not countenance such misrepresentations.

The document issued 1988 by the EPA was merely a notice that EPA was terminating an advisory program providing technical assistance to public water systems regarding how to use specific drinking water additives. That 1988 EPA notice affirmed the 1979 MOU:

> In 1979, EPA executed a Memorandum of Understanding (MOU) with the U.S. Food and Drug Administration (FDA) to establish and clarify areas of authorities with respect to control of additives in drinking water. 44 FR 42775, July 20, 1979. ... Both agencies acknowledged that in the MOU that "passage of the SDWA in

1974 repealed FDA's authority under the FFDCA over water used for drinking water purposes."

53 FR 25586, July 7, 1988, at p. 2 (copy attached at Appendix D). Prior to 1988, under its broad authority in the SDWA, the EPA had provided technical assistance and advisory opinions regarding the use of particular additive products.[28] In 1984, EPA announced its intention to transfer that program to the private sector, and in 1985 EPA awarded a cooperative agreement with funding to a National Science Foundation ("NSF") consortium to develop standards for drinking water system additives.[29] The resulting NSF standards detailing what products are appropriate for use in drinking water systems under the SDWA have been adopted throughout the United States, including the State of Washington. Under WAC 246-290-020, for example, the Washington Department of Health requires all materials coming into contact with potable water to comply with ANSI/NSF Standard 61, and requires all additives to potable water, except common bleach, to comply with ANSI/NSF Standard 60.

Since 1988, the EPA and FDA have repeatedly affirmed the 1979 MOU and the conclusion that FDA does not regulate drinking water or drinking water additives.

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[28] *See* 42 U.S.C. §§ 300j-1, 300j-2 and 300j-3; *see also* Appendix D.
[29] 53 FR 25586, July 7, 1988, at p. 2; *see* Appendix D.

- In 1993, when adopting a final rule amending standards for bottled water,[30] the FDA affirmed the continuing agreements under the 1979 MOU as follows:

  To avoid any misunderstanding, FDA notes that it does not have authority to set standards for public drinking water. Under the provisions of the SDWA of 1974, EPA is charged with ensuring that the public is provided with safe drinking water and with establishing standards for contaminants (as MCL's) in public drinking water sources. FDA, under a memorandum of understanding between EPA and FDA (44 FR 42775, July 20, 1979), is responsible for water, and substances in water, used for food and for food processing and for bottled drinking water.

  58 FR 378, January 5, 1993, at p. 3 (copy attached at Appendix E).

- In 1998, the FDA and EPA issued a joint policy interpretation regarding their respective jurisdictions under the Food Quality Protection Act of 1996. That joint policy interpretation also affirmed the 1979 MOU:

  According to the Memorandum of Understanding (MOU) between FDA and EPA on the jurisdiction over substances in drinking water (44 FR 42775, July 20, 1979), FDA has responsibility under FFDCA section 409 for water, and substances in water (including antimicrobials) used in food and in food and for food processing (44 FR 42775, July 20, 1979). ... Under the MOU, EPA has regulatory responsibility for substances added to a public drinking water system before the water enters a food processing establishment.

  63 FR 54532, October 9, 1998, at pp. 9 – 10 (at Appendix F).

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[30] The FDA regulates bottled water as a food under the FFDCA.

- In 2003, in comments on an interim rule regarding registration of food facilities under the Bioterrorism Preparedness and Response Act of 2002, the FDA again affirmed the continuing application of the 1979 MOU. 68 FR 58894, October 10, 2003, at p. 31.

As a result of the SDWA and the 1979 MOU between the FDA and EPA, it could not be more clear that the FDA does not regulate public drinking water or additives to public drinking water, much less designate them as federal legend drugs. Accordingly, there is no set of facts that Petitioners could prove showing that the FDA actually does classify the Cities' fluoridated public drinking water or the Cities' bulk fluoridation additives as federal legend drugs. If that was not clear enough, the Supreme Court ended all inquiry in its 2010 *City of Port Angeles* decision, when it specifically cited the 1979 MOU.[31]

In their Complaint, and now before this Court, Petitioners ignore that clear law. For page after page of their Opening Brief, Petitioners parse the definitions of "drug" under the FFDCA, arguing at length that the FDA **should** regulate fluoridated drinking water and fluoride additives as a drug.[32] However, in order to be a legend drug under Washington law,

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[31] *City of Port Angeles* 170 Wn.2d at 6 (f.n. 1).

[32] As noted above, even before passage of the SDWA in 1974, the FDA never regulated public drinking water as a drug under Section 201(g) of

the Cities fluoridated drinking water and bulk additives must **actually be** "designated as legend drugs under federal law" by the FDA. WAC 246-883-020. The FDA has not done so. The SDWA grants EPA "exclusive jurisdiction over drinking water served by public water supplies, including any additives in such water." 44 FR 42775, July 20, 1979, at 42776 (Appendix C). Because the Cities' drinking water and bulk additives are not designated as legend drugs under federal law, the trial court's decision dismissing Petitioners' Complaint was without doubt and must be upheld.

5.1.4 Fluoridated Public Drinking Water and the Cities Bulk Fluoridation Additives Are Not Listed in the 2009 Edition of the Drug Topics Red Book.

In addition to the requirement to be designated as a legend drug under federal law, a substance is not a legend drug under Washington law unless it is listed in the 2009 Edition of the *Drug Topics Red Book.* WAC 246-883-020(2).[33] The Complaint and

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the FFDCA (21 U.S.C. § 321(g)), but regulated public drinking water as a food under Section 201(f) of the FFDCA (21 U.S.C. § 321(f)). *See* 44 FR 42775, July 20, 1979.

[33] Petitioners cite to the definition of "prescription drug" from Ch. 246-879 WAC – the Board of Pharmacy regulatory chapter governing the licensing of pharmaceutical wholesalers. WAC 246-879-010(9). That definition merely says that a prescription drug is a drug required by state or federal law to be dispensed on prescription. Under federal law, FDA must designate a substance as requiring a prescription. Under state law, the Board of Pharmacy definition in WAC 246-883-020(2) controls what is a legend drug for purposes of Ch. 69.41 RCW.

attachments to the Complaint show clearly that this second, independent requirement of the "legend drug" definition is not met.

Petitioners' Complaint admits that drinking water and the Cities fluoridation additives are not listed in the 2009 *Drug Topics Red Book.*[34] *See* WAC 246-883-020(2).

The Complaint also attaches the relevant pages from the 2009 *Drug Topics Red Book*[35] and references those pages. The Court may consider attachments and referenced documents in a complaint when deciding a motion to dismiss. *Hirsch v. Arthur Andersen & Co.* 72 F.3d 1085, 1088, 1092 (2nd Cir. 1995) (court may consider all papers appended as well as matters of judicial notice); *Allen v. Newsome,* 795 F.2d 934, 938 (11th Cir. 1986) (report attached to complaint was considered part of the pleadings for purposes of motion to dismiss). The trial court properly considered the entire Complaint in dismissing Petitioners' claims.[36]

Each entry in the *Drug Topics Red Book* describes a specific medication compound, made by a specific manufacturer,

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[34] Complaint at ¶8 and ¶10. CP at 160.
[35] CP at 366 – 374.
[36] More legible copies of the relevant pages from the 2009 Drug Topics Red Book are included in the record at CP 35 – 44 and are attached as Appendix G to this brief.

in a specific dosage, and in a specific form of preparation and application.

Fluoridated public drinking water is not listed as any of the legend drug fluoride products in the 2009 edition of the *Drug Topics Red Book.* CP 35-44 (Appendix G).

With respect to the bulk chemical additive used by the City of Port Angeles, Petitioners admit that the City of Port Angeles utilizes tanker truck loads of bulk fluorosilicic acid as its fluoridation additive.[37] Bulk truckloads of fluorosilicic acid are not listed as a legend drug fluoride product in the 2009 edition of the *Drug Topics Red Book.* CP 35-44 (Appendix G). In fact, no form of fluorosilicic acid is listed.

With respect to the bulk chemical additive used by the City of Forks, Petitioners admit that the City of Forks utilizes 50-pound bags of bulk sodium fluoride as its fluoridation additive. Bulk sodium fluoride in 50-pound bags is also not listed in the 2009 edition of the *Drug Topics Red Book.* CP 35 – 44; *see* Appendix G. Petitioners may claim that several sodium fluoride preparations are listed in the Red Book, and make unsubstantiated assertions that all sodium fluoride in any form and in

[37] Opening Brief at 34.

every instance must therefore be a prescription drug. But it is not enough that some specific preparations of sodium fluoride for some specific uses are listed as requiring a prescription; Petitioners must prove that the specific form of sodium fluoride as used by the City of Forks requires a prescription (i.e., 50-pound bulk sodium fluoride used as a drinking water additive). *State v. Keating*, 30 Wn. App. 829, 638 P.2d 624 (1981) (in seizure action under RCW 60.41.040, state was required to prove that the ephedrine possessed by defendant was not one of the many forms of ephedrine available without prescription). By examining the very pages of the 2009 *Drug Topics Red Book* attached to the Complaint, it is obvious that Petitioners had no such proof.[38]

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[38] There are a number sodium fluoride preparations listed as prescription drugs in the *Drug Topics Red Book*, for example

- "Fluor-A-Day" sodium fluoride from Pharmascience Labs, which comes as a raspberry-flavored chewable tablet in three strengths, and as a 30-milliliter bottle of drops for topical application.
- "Fluoride" sodium fluoride tablets from Cypress Pharmaceuticals, which is a chewable tablet that comes in both lemon and grape flavors.
- "Fluorinse" topical rinse from Oral B Laboratories, which is a 2% solution that comes in a 480-milliliter bottle in either cinnamon or mint flavors.
- "Fluoritab" brand of sodium fluoride from Fluoritab, which comes in both chewable tablets (cherry flavor) or in a 23-milliliter bottle of drops for topical application.
- U. S. Pharmacopeia sodium fluoride for formulary use in amounts up to 2270 grams (approx. five pounds).

The mere fact that there are some preparations using sodium fluoride listed in the *Drug Topics Red Book* does not mean that every product including sodium fluoride is a legend drug that a court may seize under RCW 69.41.060. To rule otherwise would mean that this court could seize every tube of fluoride toothpaste sold in every supermarket in the state that contains any amount of sodium fluoride. The Court must recognize the absurdity of that argument.

Petitioners argued broadly below, and are expected to argue in reply, that all fluoride is regulated as a legend drug. Petitioners have based this argument almost entirely on a single sentence (taken out of context) from a June 3, 2009 letter written by the Board of Pharmacy and attached to the Complaint.[39] Even if the Court were to consider the letter, it only demonstrates the continued futility of Petitioners' claims.

The 2009 letter was not rulemaking or an official interpretation from the Board of Pharmacy. The Court must look at the entire letter when interpreting its meaning, rather than the single sentence quoted out

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See 2009 *Drug Topics Red Book* pages at attached Appendix G. None of these flavored topical rinses, flavored chewable tablets, formulary products for pharmacists, or toothpaste gels are the same as the bulk fluoride shipments in 50-pound bags for use as a drinking water additive by the City of Forks.

[39] CP at 360 – 365. The letter is an informal response and is neither law nor regulation.

of context by Petitioners. *Mader v. Health Care Auth.*, 70 P.3d 931, 149 Wn.2d 458 (2003) (when interpreting a document, the entire document must be considered). The letter is a response to another anti-fluoride advocate, who had requested the Board of Pharmacy designate fluoride (in all forms) as a poison. In the letter, the Board explains how prescription fluoride drugs are regulated – they just be designated federal legend drugs by the FDA and listed in the *Drug Topics Red Book*:

> In WAC 246-883-020(2), the Board specified that "legend drugs are drugs which have been designated as legend drugs under federal law and are listed as such in the 2002 edition of the *Drug Topics Red Book*." [The current regulation uses the 2009 edition.] Enclosed are copies of pages 169, 342, and 690 of the Drug Topics Red Book. Page 169 is the key to the products requiring prescription (legend drugs) and page 342 contains the fluoride products. Page 690 contains the listing of over-the-counter fluoride products, primarily toothpaste containing fluoride.[40]

The Board says exactly what the Cities have stated throughout this case (and exactly what was known to Petitioners) – to be a legend drug, a substance must be designated (by FDA) as a federal legend drug, and it must be listed in the 2009 *Drug Topics Red Book.*

Because neither fluoridated public drinking water nor the bulk additives used by the Cities in their fluoridation programs are listed in the 2009 edition of the *Drug Topics Red Book*, they are not "legend drugs"

under Washington law. For this independent reason, the trial court properly dismissed Petitioners' Complaint.

5.1.5 The City of Port Angeles Case Is Dispositive of Petitioners' Claims.

In violation of its obligation to the Court, Petitioners try to ignore the holding of the *City of Port Angeles* case, which held that fluoride is a permitted chemical additive to public drinking water under Washington law.[41] In that case, the Washington Supreme Court explains exactly how public drinking water systems, and drinking water fluoridation, is regulated in the State of Washington:

> The Washington State Legislature vested the Department of Health with the power and duty to regulate the health and safety of drinking water. RCW 43.20.050(2)(a). [footnote omitted] The department has responded with detailed regulations governing public water systems. Ch. 246-290 WAC. This chapter includes a specific regulation on fluoridation, WAC 246-290-460. Pursuant to the SDWA and the regulations promulgated by Washington's Department of Health, there are approximately 40 chemicals that may be added to public water supplies. ... **Fluoride is one of the permitted chemicals**. WAC 246-290-460.

City of Port Angeles, 170 Wn. 2d at 8 – 9 (emphasis added).

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[40] CP at 46 – 50.
[41] *City of Port Angeles*, 170 Wn.2d at 8 – 9.

Petitioners' argument here, that fluoride is not a permitted chemical in public drinking water, is a meritless claim directly contradicted by the holding of the Washington Supreme Court in *City of Port Angeles*.[42] The Cities' public drinking water systems are comprehensively regulated by the Washington Department of Health and Board of Health. The Department of Health regulations "permit water systems to administratively adopt water fluoridation programs;"[43] and fluoride additives are expressly allowed by those regulations.[44] Because the Supreme Court has already held that the Cities' fluoridation systems, as regulated by the Department of Health, are lawful and permitted public water systems, Petitioners' Complaint was properly dismissed.

Petitioners' only response to *City of Port Angeles* is to claim that Court's conclusion regarding the 1979 MOU was *dicta*. Petitioners are incorrect. The discussion to the 1979 MOU in *City of Port Angeles* was part of the Court's legal holding. The decision in *City of Port Angeles* involved proposed initiatives that would have overturned the City's decision to fluoridate its water system. A key component of one initiative

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[42] *Id.*
[43] *City of Port Angeles*, 170 Wn.2d at 12.
[44] *Id.* at 9.

was that fluoride could not be added to public water systems unless approved by the FDA. The Court held that "the FDA exception is essentially meaningless since the Environmental Protection Agency, not the FDA, regulates public drinking water systems." *City of Port Angeles*, 170 Wn. 2d at 6 (citing to the 1979 MOU).

The Supreme Court has already held, in *City of Port Angeles*, that drinking water fluoridation systems and fluoride additives regulated by the Department of Health are lawful under Washington law.[45] That alone was enough for the trial court to dismiss Petitioners' Complaint.[46]

5.2 The Trial Court Properly Denied Petitioners' Motion to Amend Their Complaint.

5.2.1 Standard of Review.

Motions to amend pleadings are within the discretion of the trial court. This Court applies the abuse of discretion standard and will not overturn the trial court unless the trial court was manifestly unreasonable, or exercised its discretion on untenable grounds or for untenable reasons. *Wilson v. Horsley*, 137 Wn.2d 500, 505, 974 P.2d 316 (1999).

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[45] *City of Port Angeles*, 170 Wn.2d at 8 – 9

[46] As later argued in this brief, Petitioners' claims in the face of the Supreme Court's holdings in *City of Port Angeles*, should have resulted in an award of fees and costs to the Cities.

The Court may uphold the trial court on any ground substantiated by the record, whether or not that ground was considered dispositive by the trial court. *Reed v. Streib,* 65 Wn.2d 700, 709, 399 P.2d 338 (1965); *Mooney v. American Mail Line, Ltd.*, 61 Wn.2d 181, 183, 377 P.2d 429 (1963).

5.2.2 The Trial Court Correctly Held That Petitioners' Motion to Amend Was Futile.

A motion for leave to amend should be denied if the proposed amendment would be futile. *Rodriguez v. Loudeye Corp.*, 144 Wn. App. 709, 729, 189 P.3d 168 (2008) ("Denying a motion for leave to amend is not an abuse of discretion if the proposed amendment is futile."); *Shelton v. Azar, Inc.*, 90 Wn. App. 923, 928, 954 P.2d 352 (1998) (the trial court abused its discretion when it granted a motion to amend because pursuing the new claim would be futile). A proposed amendment is futile if the new claim is legally defective. *See Rodriguez*, 144 Wn. App. at 729; *see also Miller v. Rykoff-Sexton, Inc.*, 845 F.2d 209, 214 (9th Cir. 1988).

On the eve of the hearing on the Cities' motion to dismiss, Petitioners moved to amend their Complaint. The amendment sought to add a claim for declaratory judgment as to whether the Cities' fluoridated public drinking water and additives were "drugs."[47] The trial court denied the amendment as futile,[48] explaining that the Supreme Court had already

[47] CP at 200 – 202.
[48] CP at 12 – 13.

decided that providing fluoridated drinking water was not dispensing a drug in *Kaul v. Chehalis*, 45 Wn.2d 616, 625, 277 P.2d 352 (1955).[49] Two other reasons to deny amendment were also presented to the trial court, and under any of those three theories the trial court ruled correctly.

5.2.2.1 The Proposed Amendment Was Not Necessary for the Court to Determine Whether Fluoridated Drinking Water Is a Legend Drug.

Petitioners' only justification for the proposed amendment was the assertion that the trial court needed to determine whether fluoridated drinking water was a "drug" before it could determine whether it was a "legend drug."[50]

As discussed above, the Board of Pharmacy's definition of "legend drug" is unambiguous, and that definition does not require an initial inquiry as to whether a substance is a "drug." WAC 246-883-020. To be a legend drug under Washington law, a substance must be designated as a legend drug under federal law and be listed in the *Drug Topics Red Book*. As discussed in detail above in this brief, neither requirement can be met. Accordingly, with or without Petitioners' proposed amendment, the Complaint would have to be dismissed, and Petitioners' proposed amendment was futile (as well as frivolous).

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[49] VRP at 10, lines 5 – 11.

5.2.2.2 Controlling Case Law from the Washington Supreme Court, and Throughout the Country, Holds that Fluoridated Drinking Water Is Not a Drug.

Petitioners' proposed amendment to the Complaint was also futile because courts throughout the country, including the Washington Supreme Court, have consistently and uniformly held that fluoridated drinking water is **not** a drug. *Kaul v. Chehalis*, 45 Wn. 2d 616, 625, 277 P.2d 352 (1955) (when City of Chehalis provided fluoridated drinking water "the city is not engaged in selling drugs"); *Dowell v. Tulsa*, 273 P.2d 859, 864 (Ok. 1954) ("[I]n the contemplated water fluoridation, the City of Tulsa is no more practicing medicine or dentistry or manufacturing, preparing, compounding or selling a drug, than a mother would be who furnishes her children a well-balanced diet, including foods containing vitamin D and calcium to harden bones and prevent rickets, or lean meat and milk to prevent pellagra. No one would contend that this is practicing medicine or administering drugs."); *Kraus v. City of Cleveland*, 127 N.E.2d 609, 635 (Ohio 1955) (fluoridation of public water supply held not to be the practice of medicine or providing a drug).

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[50] CP 201.

Petitioners claim that the statements in *Kaul* were dicta. Again, Petitioners are incorrect and misstate the law to the Court. In *Kaul*, one of the assignments of error was that the City of Chehalis was engaged in selling drugs and practicing medicine without a license by distributing fluoridated public drinking water. *Kaul*, 45 Wn.2d at 625. The Court disposed of that assignment of error summarily, and upheld the trial court's conclusion of law that the City of Chehalis was "not engaged in selling drugs, practicing medicine, dentistry, or pharmacy as defined by statute." *Id.* This is not dicta, but is a holding of the Court on a specific assignment of error in that case.

Beyond *Kaul*, the obvious conclusion that fluoridated drinking water is not a drug is shown by the clear and separate grants of authority by the Washington Legislature. The Legislature has granted the Board of Pharmacy the authority to promulgate rules pertaining to drugs. RCW 18.64.005(7). The Legislature has granted regulatory authority to the Board of Health and Department of Health to regulate public drinking water and water additives. RCW 42.30.050(2); *City of Port Angeles*, 170 Wn.2d at 8–9.

The Board of Pharmacy has enacted regulations governing both prescription drugs and over the counter drugs. Chapter 246-883 WAC; WAC 246-885-030. None of the Board of Pharmacy regulations govern

public drinking water or drinking water additives. The Board of Health and Department of Health, on the other hand, have enacted detailed regulations governing public drinking water and drinking water additives. Chapter 246-290. Those regulations expressly allow fluoride as an additive to public drinking water. WAC 246-290-490; *City of Port Angeles*, 170 Wn.2d at 8–9, 12.

Because the Washington Supreme Court has already determined that fluoridated public drinking water is not a drug, and because fluoridated drinking water and water additives are not regulated as drugs under Washington law, Petitioners' proposed amendment to the Complaint was futile.

5.2.2.3 The Proposed Amendment Addresses Issues Within the Primary Jurisdiction of the Washington Board of Pharmacy and Department of Health

Under the doctrine of primary jurisdiction, when a claim requires the resolution of issues that, under a regulatory scheme, have been placed within the special competence of an administrative agency, the judicial process should defer the matter to that administrative body. *In re Real Estate Brokerage Antitrust Litigation v. Coldwell Banker Residential Brokerage Co.*, 95 Wn.2d 297, 302, 622 P.2d 1185 (1980). As discussed by the Supreme Court in the *City of Port Angeles* case, public drinking

water and drinking water fluoridation programs are comprehensively regulated by the Washington Department of Health.

> The Washington State Legislature vested the Department of Health with the power and duty to regulate the health and safety o drinking water. RCW 43.20.050(2)(a). [footnote omitted] The department has responded with detailed regulations governing public water systems. Ch. 246-290 WAC. This chapter includes a specific regulation on fluoridation, WAC 246-290-460. Pursuant to the SDWA and the regulations promulgated by Washington's Department of Health, there are approximately 40 chemicals that may be added to public water supplies. ... Fluoride is one of the permitted chemicals. WAC 246-290-460.

City of Port Angeles, 170 Wn. 2d at 8 – 9.

The Legislature has authorized the Board of Health to promulgate standards for additives to public drinking water. RCW 42.30.050(2); *see* Ch. 246-290 WAC. The Legislature has granted the Board of Pharmacy the authority to promulgate rules pertaining to dispensing and distribution of drugs. RCW 18.64.005(7). The Board of Pharmacy has done so, but none of those rules regulate public drinking water or regulate fluoride additives in public drinking water. Chapters 246-856 through 246-907 WAC.

Petitioners disagree with how the Department of Health and the Board of Pharmacy regulate fluoride in public drinking water. Under the

doctrine of primary jurisdiction, it is not up to the Court to re-write the administrative regulations adopted by those expert agencies.

The Washington Administrative Procedures Act has a procedure by which Petitioners can petition the Department of Health or Board of Pharmacy to adopt, repeal or amend any rule. RCW 34.05.330. The state agency can initiate rulemaking to adopt the requested rule or deny the request. *Id.* If denied, further relief is available under the Administrative Procedures Act. RCW 34.05.330(3); RCW 34.05 510 *et seq.* This provides Petitioners with a full and complete remedy to determine whether fluoridated drinking water should be regulated as a "drug" under Washington law. Because Petitioners' proposed amendment was within the primary jurisdiction of those agencies, the proposed amendment was futile and was properly denied by the trial court.

By their frequent reference to the administrative regulations in the Complaint, it is obvious that Petitioners understand the regulatory framework. Yet Petitioners intentionally ignore the available administrative process and attempt to use this Court as a political platform. This Court should not tolerate such behavior.

5.3 Petitioners' Constitutional Challenges to Board of Health and Department of Health Regulations Were Not Raised Below and Should Not Be Considered.

The general rule is that appellate courts will not consider issues raised for the first time on appeal. *State v. Kirkman*, 159 Wn.2d 918, 926, 155 P.3d 125 (2007); *State v. Tolias*, 135 Wn.2d 133, 140, 954 P.2d 907 (1998); RAP 2.5(a). The appellate court may consider "manifest errors affecting a constitutional right." RAP 2.5(a)(3). In order to show manifest error, however, the appellant must identify a constitutional error and show how the alleged error actually affected the appellant's rights at trial.

In their Opening Brief, Petitioners argue for the first time, with no citation to authority, that several regulations of the Board of Health and the Department of Health violate the Supremacy Clause of the U. S. Constitution, Art. VI, Cl. 2, because the FDA is required to regulate drugs before they can be marketed. The regulations alleged to violate the Supremacy Clause are the Board of Health regulation requiring public water systems to meet the ANSI/NSF Standard 60 for all water additives, and the Department of Health regulation specifying fluoridation levels if a public water system practices fluoridation. WAC 246-290-220(3); WAC 246-290-460(2) & (3).

Primarily, an argument without citation to authority will not be considered by the Court. *See State v. Woods*, 89 Wn.2d 97, 99, 569 P.2d 1148 (1977). Secondarily, Petitioners have not even attempted to show any manifest error that affected their rights in the trial court, as required by RAP 2.5(a)(3). Thus, Petitioners' new arguments should not be considered by this Court.

Should the Court reach the merits, Petitioners' argument is specious. First, while the Supremacy Clause is a constitutional principle, it is not a constitutional "right" to which RAP 2.5(a)(3) would apply. Second, Petitioners' make no argument as to how the Board of Health and Department of Health regulations might conflict with federal law; and the contrary is shown the Supreme Court's *City of Port Angeles* decision. The regulations cited merely state that if a water system practices fluoridation, it must comply with these comprehensive state regulations. They do not require fluoridation or conflict with FDA's authority under the FFDCA. Third, as discussed in detail above, Congress has delegated the regulation of public drinking water to the EPA, not the FDA; and the FDA itself has consistently taken the position that it has no jurisdiction to regulate drinking water or drinking water additives. 42 U.S.C. § 300g-1; 44 FR 42775, July 20, 1979 (Appendix C); 63 FR 54532, October 9, 1998, at pp. 9 – 10 (Appendix F). Every court to consider the issue, including the

Washington Supreme Court, agrees that FDA does not have jurisdiction of public drinking water or drinking water additives. *City of Port Angeles*, 170 Wn.2d at 6 (f.n. 1); *Coshow v. City of Escondido*, 132 Cal. App. 4th at 713. Because there is no federal regulation of drinking water by FDA, it is frivolous to argue there is conflict with FDA's authority. Petitioners' arguments are meritless and further demonstrate the basis for an award of fees and costs to the Cities.

5.4 The Court Should Overturn the Trial Court's Denial of Costs and Attorneys' Fees, Because a Reasonable Inquiry Would Have Revealed the Absence of Any Factual or Legal Basis for Petitioners' Claim, and Should Award Costs and Attorneys' Fees for Petitioners' Frivolous Appeal.

The utility ratepayers of the City of Port Angeles and the City of Forks will pay for defense of this baseless lawsuit and this frivolous appeal unless the Court protects those ratepayers. The public drinking water systems provided by the Cities have been approved by the Washington Department of Health, and the Department of Health specifically allows fluoride additives to those public drinking water systems. That regulatory program and the legality of fluoridation has been affirmed by this Court. This lawsuit was brought without any reasonable basis in fact and is clearly not warranted by existing law. Essentially, Petitioners seek to make a political point – they oppose fluoridation of public drinking water, and they believe the FDA should regulate drinking

water fluoridation as a drug. But the FDA does not. If the courts do not discourage these types of cases, the courts will continue to be sources for political expression, rather than judicial dispute resolution. The Court must not only reject this action, but should also impose terms to discourage such lawsuits and to protect the utility ratepayers of the Cities. Both RCW 4.84.185 and CR 11 provided a basis for awarding costs and attorneys' fees in the trial court. RAP 18.9(a) provides a basis for awarding costs and attorneys' fees on appeal.

5.4.1 The Trial Court Erred in Denying the Cities' Request for Costs and Attorneys' Fees Below.

The trial court's denial of the Cities' request for costs and reasonable attorneys' fees is reviewed for abuse of discretion. *Washington State Physician Ins. Exch. & Ass'n v. Fisons Corp.*, 12 Wn.2d 299, 88 P.2d 1054 (1993). The trial court abuses its discretion if it applies an incorrect legal standard or applies incorrect legal analysis. *Dix v. ICT Group, Inc.*, 160 Wn.2 826, 833, 161 P.3d 1016 (2007); *In re Welfare of B.R.S.H.*, 141 Wn. App. 39, 56, 169 P.3d 40 (2007).

Before the trial court, the Cities requested costs and attorneys' fees under both RCW 4.84.185 and under CR 11. The trial court applied the incorrect legal standard to the Cities' request – the trial court denied the Cities request solely because the trial court believed that Petitioners were

arguing for a good faith change in the law. VRP at 40 lines 2 – 5. Application of an incorrect legal standard is an abuse of discretion and reversible error.

5.4.1.1 The Cities Should Be Awarded Costs and Reasonable Attorneys' Fees Under RCW 4.84.185.

Washington law permits a prevailing party to recover attorneys' fees and costs incurred when defending against a frivolous lawsuit. RCW 4.84.185. The statute was passed to discourage parties from filing frivolous lawsuits and "to compensate the targets of such lawsuits for fees and expenses incurred in fighting meritless cases." *Kearney v. Kearney*, 95 Wn. App. 405, 416, 974 P.2d 872 (1999), *quoting*, *Biggs v. Vail*, 119 Wn.2d 129, 137, 830 P.2d 350 (1992). A suit is frivolous if it is not supported by any rational argument based on the law or the facts. *See Déjà Vu-Everett-Federal Way, Inc. v. City of Federal Way*, 96 Wn. App. 255, 264, 979 P.2d 464 (1999) (holding that when a claim was barred by the doctrines of collateral estoppel and res judicata it was abuse of discretion to deny the defendant its motion for fees and costs).

In this case, Petitioners' claims are that the fluoridated water in the Cities' public water systems, and the fluoridation additives that have been approved by the Department of Health, are legend drugs that a court may seize under RCW 69.41.060. Petitioners' claims are not supported by a

rational argument based on the applicable law and the facts. Petitioners have a political, not a legal, argument. They believe that the Congress, the FDA and EPA, the Washington Legislature, and the Department of Health and Board of Pharmacy should regulate drinking water fluoridation differently. The trial court correctly noted that Petitioners' remedy is with the Legislature, not with the Courts. Based the incontestable facts applicable to this case, Petitioners' legal claims are neither reasonable nor rational.

Petitioners and their attorney were aware of the Board of Pharmacy definition of 'legend drugs" and even cite that regulation in their Complaint.[51] There is no rational argument that definition of legend drugs, which requires FDA designation as a federal legend drug and listing in the 2009 *Drug Topics Red Book*, can be met in this case. WAC 246-883-020(2). Petitioners may believe that the FDA *should* regulate fluoridated water and fluoridation additives, and designate them as federal legend drugs, but it is beyond question that the FDA has *not* done so. Petitioners have known since at least last year's *City of Port Angeles* case that the FDA does not regulate public drinking water. *City of Port Angeles*, 170 Wn.2d at 6 (f.n. 1). The FDA itself has repeatedly provided

[51] CP at 160.

formal notices in the Federal Register that, since the passage of the SDWA, the FDA has no jurisdiction to regulate public drinking water and drinking water additives. 44 FR 42775, July 20, 1979 (Appendix C); 63 FR 54532, October 9, 1998, at pp. 9 – 10 (Appendix F). Petitioners ignore the FDA's interpretation of its jurisdiction; and it is beyond argument that FDA has not taken action to designate fluoridated drinking water and fluoridation additives to drinking as federal legend drugs. So it is impossible for fluoridated drinking water and drinking water additives to be legend drugs under the Board of Pharmacy definition in WAC 246-883-020(2).

Similarly with the second independent requirement to be a legend drug under Washington law, Petitioners admit in their Complaint that the fluoride additives used by the Cities are not listed in the 2009 *Drug Topics Red Book.*[52] The pages from the *Drug Topics Red Book* attached to the Complaint confirm that fluoridated drinking water and the bulk additives used by the Cities are not listed. Petitioners also participated in the 2010 *City of Port Angeles case*, which was brought by the same attorney, and knew that the Washington Supreme Court determined that fluoride is a permitted chemical additive to public drinking water.

[52] Complaint ¶¶ 6, 8, 10; CP at 159 – 160.

The legal standard for an award of costs and reasonable attorneys' fees under RCW 4.84.185 is whether the Complaint is supported by a rational argument based on the law or the facts – not whether the Petitioners are arguing for a good faith change in the law. Given the controlling legal definition for legend drugs, there is no rational argument that the Cities' drinking water and additives are legend drugs. Accordingly, the Court must overturn the trial court's denial of the Cities' request and remand for an award to the Cities of their costs and attorneys fees.

5.4.1.2 The Cities Should Be Awarded Costs and Reasonable Attorneys' Fees Under CR 11.

Alternately, CR 11 provides sanctions for baseless filings that are not well grounded in fact or law and the result of inadequate investigation:

> The signature of a party or of an attorney constitutes a certificate by the party or attorney that the party or attorney has read the pleading, motion, or legal memorandum; that to the best of the party's or attorney's knowledge, information, and belief, formed after reasonable inquiry, it is well grounded in fact **and** is warranted by existing law or a good faith argument for the extension, modification, or reversal of existing law, and that it is not interposed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

CR 11 (emphasis supplied). A filing violates CR 11 if it is either (1) not well-grounded in fact or (2) not warranted by existing law or the good faith argument for the alteration of existing law. *MacDonald v. Korum*

Ford, 80 Wash. App. 877, 883-84, 912 P.2d 1052 (1996). The trial court denied the Cities' request under CR 11 because the court believed Petitioners were arguing for a good faith change in the law. But that is not the only standard in CR 11. Petitioners' claims also had to well grounded in fact, after a reasonable enquiry; and Petitioners' claims fail that test.

In *McDonald*, for example, the claim was not well-grounded in fact when it became obvious after plaintiff's deposition that the hostile workplace claim was not supported. *McDonald*, 80 Wn. App. 877. In *Rhinehart v. Seattle Times*, a claim was neither warranted by existing law nor well-grounded in fact when most of the issues in a defamation case had been raised and rejected in prior cases and where the case was so devoid of merit that there was no reasonable possibility of success. *Rhinehart v. Seattle Times*, 59 Wn. App. 332, 798 P.2d 1155 (1990).

In this case, the claims in the Complaint are not well grounded in fact. It is an indisputable fact that the FDA has not designated fluoridated public drinking water supplies and fluoridation additives as federal legend drugs. Similarly, it is indisputable that fluoridated public drinking water and the fluoridation additives used by the Cities are not listed in the 2009 *Drug Topics Red Book*. Because the legal definition of legend drug under Washington law can never be met, given those incontrovertible facts, Petitioners claims were not well grounded in fact and were not the result of a reasonable inquiry, and the trial court erred when it did not award the Cities their reasonable costs and attorneys' fees under CR 11.

5.4.1.3 The Cities Should Be Awarded Costs and Reasonable Attorneys' Fees On Appeal Under RAP 18.9(a).

The Cities move under RAP 18.9(a) for an award of fees and costs on appeal. Under RAP 18.9(a), this Court may require a party to pay the fees of another party for defending a frivolous appeal. *Green River Cmty. Coll. Dist. No. 10 v. Higher Educ. Pers. Bd.* 107 Wn.2d 427, 442-43, 730 P.2d 653 (1986) (pursuing a frivolous appeal justifies the imposition of terms and compensatory damages). An appeal is frivolous if there are no debatable issues upon which reasonable minds might differ and it is so totally devoid of merit that there was no reasonable possibility of reversal. *Eugster v. City of Spokane*, 139 Wn. App. 21, 34, 156 P.3d 912 (2007).

As discussed in detail above, there are no debatable issues with respect to the controlling law and facts in this case. Petitioners' political agenda, that fluoridated drinking water should be regulated differently, is not an excuse. There are no debatable issues about whether the Cities' fluoridated public drinking water, and the additives used by the Cities, are legend drugs subject to seizure under RCW 69.41.060.

Petitioners and their attorney have brought this appeal as a political statement. The appeal has no merit and is a clear case for an award of costs and fees on appeal under RAP 18.9(a). The Court should put a stop to Petitioners' frivolous conduct, which burdens both the Cities' utility ratepayers and the courts.

6. CONCLUSION

For the foregoing reasons, the City of Port Angeles and the City of Forks respectfully request the Court to uphold the trial court's dismissal of Petitioners' Complaint, to uphold the trial court's denial of Petitioners' motion to amend, to hold that the Cities should be awarded their reasonable attorneys' fees and expenses in the trial court, and to award the Cities their reasonable attorneys' fees and expenses for having to defend this frivolous appeal.

RESPECTFULLY SUBMITTED this 19th day of December 2011.

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APPENDICES

A. Order Granting Defendant Cities' Motion To Dismiss (CP 7 – 11).

B. Order Denying Motion To Amend Complaint (CP 12 – 13).

C. Memorandum of Understanding between FDA and EPA, 44 FR 42775 (July 20, 1979). (CP 30 – 33).

D. 53 FR 25586 (July 7, 1988).

E. 58 FR 378 (January 5, 1993).

F. 64 FR 54532 (October 9, 1998).

G. 2009 Drug Topics Red Book, selected pages (CP 35 – 44).

APPENDIX A

FILED

2011 JUN 17 PM 2:03

IN SUPERIOR COURT
JEFFERSON COUNTY CLERK

SUPERIOR COURT OF WASHINGTON IN AND FOR CLALLAM COUNTY

PROTECT THE PENINSULA'S FUTURE, CLALLAM COUNTY CITIZENS FOR SAFE DRINKING WATER, and ELOISE KAILIN,

Petitioners,

v.

CITY OF PORT ANGELES, and CITY OF FORKS ,

Defendants.

The Honorable Craddock Verser,
Visiting Judge
Hearing Date: June 17, 2011 @ 1:00 PM

No. 11-2-00433-6

ORDER GRANTING DEFENDANT CITIES' MOTION TO DISMISS

[Proposed]

This matter came before the Court on Defendant Cities' Motion To Dismiss (the "Motion") brought by Defendants City of Port Angeles and City of Forks (the "Cities"). The Court read and considered the pleadings and files in this action, the Motion, the responding materials from Petitioners, and the reply materials from Defendants. The Court also heard and considered argument of counsel for both parties. Deeming itself fully advised, the Court finds as follows:

1. The Cities each operate a public drinking water utility.

2. The Cities each provide a fluoridation program for their public drinking water utility.

3. In the Complaint in this action, the plaintiffs ask the Court to issue a search and seizure warrant under RCW 69.41.060 to seize the Cities fluoridation systems and any bulk

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fluoridation additives used in connection with those systems. Plaintiffs claim that the Cities' fluoridated drinking water and those fluoridation additives are "legend drugs" requiring a prescription under Chapter 69.41 RCW and that are being distributed in violation of that chapter.

4. The Washington Supreme Court held in City of *Port Angeles v. Out Water–Our Choice*, 170 Wn.2d 1 (2010) that under federal law the U.S. Environmental Protection Agency ("EPA") regulates public drinking water and allows for greater state regulation; the Washington Legislature vests the Department of Health with state regulatory authority; that the Washington Department of Health regulations permit public water systems (such as the Cities' systems) to adopt a water fluoridation program; the Department of Health regulations include a specific regulation of fluoride; and the Department of Health specifically permits fluoride additives to public drinking water systems.

5. The U.S. Food and Drug Administration is the federal agency regulating all prescription drugs. The FDA has given notice in the Federal Register that it does not regulate public drinking water or additives to public drinking water; and the Supreme Court in *City of Port Angeles* confirmed that the FDA does not regulate public drinking water or additives to public drinking water.

6. In order to be classified as a "legend drug" for purposes of Chapter 69.41 RCW, the Washington Board of Pharmacy regulations require that a drug must meet two requirements: a) it must be classified as a legend drug under federal law; and b) it must be listed as such in the 2009 edition of the *Drug Topics Red Book*. WAC 246-883-020.

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7. Because the FDA does not regulate public drinking water or drinking water additives, it is impossible for plaintiffs to prove that the first requirement for being a "legend drug" under Washington law is met.

8. The Complaint and the attachments thereto show that neither public drinking water nor fluoridation additives to public drinking water are listed as a legend drug in the 2009 edition of the *Drug Topics Red Book*. Therefore, it is also impossible for plaintiffs to prove that the second requirement for being a "legend drug" under Washington law is met.

9. Accordingly, there is no set of facts plaintiffs can prove that would show the Cities' public drinking water or the Cities' fluoride additives for drinking water fluoridation (as permitted by the Department of Health) are legend drugs, and the Complaint should be dismissed pursuant to CR 12(b)(6).

10. Plaintiffs and their counsel were well aware of the decision of the Washington Supreme Court providing that fluoride additives to public drinking water are permitted by the Washington Department of Health. Plaintiffs and their counsel are also well aware of the definition of "legend drugs" in WAC 246.883-020 and cited that regulation in the Complaint. Plaintiffs were aware that neither requirement of that definition was met because fluoride additives to public drinking water are not classified as "legend drugs" under federal law and because fluoride additives to public drinking water are not listed legend drugs in the 2009 edition of the *Drug Topics Red Book*.

11. Accordingly the claim brought in the Complaint is not well grounded in fact or warranted by existing law or a good faith argument for the extension, modification or reversal of

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existing law as required by Civil Rule 11. The claim brought in the Complaint is also frivolous and meritless for purposes of RCW 4.84.185.

12. It is appropriate to award terms under CR 11 and RCW 4.84.185 in order to protect the ratepayers of the City of Port Angeles and City of Forks utilities from this type of vexatious and meritless litigation.

Based on the foregoing findings, it is accordingly ORDERED, ADJUDGED and DECREED as follows:

A. Plaintiffs' Certified Complaint For Search And Seizure Warrants should be, and hereby is, DISMISSED WITH PREJUDICE.

B. Defendants City of Port Angeles and City of Forks are hereby awarded their costs and reasonable attorneys fees expended in the defense of this action pursuant to CR 11 against Petitioners and Petitioners' counsel jointly and severally.

C. Defendants City of Port Angeles and City of Forks are hereby awarded their costs and reasonable attorneys fees expended in the defense of this action pursuant to RCW 4.84.185 against Petitioners jointly and severally.

D. Defendants shall present a Cost Bill for consideration of the Court pursuant to Court Rule.

DATED this 12 day of June 2011.

HON. CRADDOCK VERSER, Superior Court Judge

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Presented by:

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Roger A Pearce for
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APPENDIX B

FILED
CLALLAM COUNTY
JUN 14 2011
BARBARA CHRISTENSEN CLERK

SUPERIOR COURT OF WASHINGTON IN AND FOR CLALLAM COUNTY

PROTECT THE PENINSULA'S FUTURE, CLALLAM COUNTY CITIZENS FOR SAFE DRINKING WATER, and ELOISE KAILIN, Petitioners, v. CITY OF PORT ANGELES, and CITY OF FORKS , Defendants.	The Honorable Craddock Verser, Visiting Judge Hearing Date: June 17, 2011 @ 1:00 PM No. 11-2-00433-6 ORDER DENYING MOTION TO AMEND COMPLAINT

This matter came on regularly before the Court on June 17, 2011, on the Motion to Amend Complaint ("Motion") brought by Petitioners Protect the Peninsula's Future, Clallam County Citizens for Safe Drinking Water, and Eloise Kailin. The Court read and considered the pleadings and files in this action, the Motion, and the responding materials from Defendants. The Court also heard and considered argument of counsel for both parties. Deeming itself fully advised, the Court: finds that the amendment to the Complaint would be futile for the reasons described by Judge Verser in the record.

ORDERED, ADJUDGED and DECREED as follows:

Petitioners' Motion to Amend Complaint should be, and hereby is, DENIED.

//

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//

DATED this 23rd day of June 2011.

Judge Craddock Verser

HON. CRADDOCK VERSER, Superior Court Judge

Presented by:

WILLIAM E. BLOOR, City Attorney,
City of Port Angeles

Roger A Pearce for
William E. Bloor, WSBA #4084

WILLIAM R. FLECK, City Attorney,
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Roger A Pearce
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Roger A. Pearce, WSBA #21113
Attorneys for defendants City of Port Angeles and City of Forks

Agreed as to form; notice of presentation waived.

GERALD STEEL, PE

Gerald Steel, WSBA # 31084
Attorney for petitioners Protect the Peninsula's Future, Clallam County Citizens for Safe Drinking Water, and Eloise Kailin

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APPENDIX C

Federal facilities. Prior to making a final recommendation to the Administrator, U.S. EPA, the Regional Administrator, Region V, is providing opportunity for public comment on the State of Wisconsin request. Any interested person may comment upon the State request by writing to the U.S. EPA, Region V Office, 230 South Dearborn Street, Chicago, Illinois 60604, Attention: Permit Branch. Such comments will be made available to the public for inspection and copying. All comments or objections received by August 22, 1979, will be considered by U.S. EPA before taking final action on the Wisconsin request for authority to issue permits to Federal facilities.

The State's request, related documents, and all comments received are on file and may be inspected and copied (@ 20 cents/page) at the U.S. EPA, Region V Office, in Chicago.

Copies of this notice are available upon request from the Enforcement Division of U.S. EPA, Region V, by contacting Dorothy A. Price, Public Notice Clerk (312-353-2105), at the above address.

Dated: July 13, 1979.

John McGuire,

Regional Administrator.

[FR Doc. 79-22372 Filed 7-19-79; 8:45 am]

BILLING CODE 6560-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1275-4]

Drinking Water Technical Assistance; Implementation Plan for Control of Direct and Indirect Additives to Drinking Water and Memorandum of Understanding Between the Environmental Protection Agency and the Food and Drug Administration

AGENCY: Environmental Protection Agency and Food Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have executed a memorandum of understanding (MOU) with regard to the control of direct and indirect additives to and substances in drinking water. The purpose of the MOU is to avoid the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives. The agreement became effective on June 22, 1979.

ADDRESS: Submit comments to: Victor J. Kimm, Deputy Assistant Administrator for Drinking Water, Environmental Protection Agency (WH-550), Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: David W. Schnare, Ph.D., Office of Drinking Water (WH-550), Environmental Protection Agency, Washington, D.C. 20460, (202) 755-5643; or Gary Dykstra, Enforcement Policy Staff (HFC-22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-3470.

SUPPLEMENTARY INFORMATION: In the spirit of interagency cooperation and to avoid the possibility of overlapping jurisdiction over additives and other substances in drinking water, FDA and EPA have entered into a memorandum of understanding to avoid duplicative and inconsistent regulation. In brief, the memorandum provides that EPA will have primary responsibility over direct and indirect additives and other substances in drinking water under the Safe Drinking Water Act, the Toxic Substances Control Act, and the Federal Insecticide, Fungicide and Rodenticide Act. FDA will have responsibility for water, and substances in water, used in food and for food processing and for bottled water under the Federal Food, Drug and Cosmetic Act.

Pursuant to the notice published in the Federal Register of October 3, 1974, (39 FR 35697) stating that future memoranda of understanding, and agreements between FDA and others would be published in the Federal Register, the following memorandum of understanding is issued:

Memorandum of Understanding Between the Environmental Protection Agency and the Food and Drug Administration

I. Purpose

This Memorandum of Understanding establishes an agreement between the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) with regard to the control of direct and indirect additives to and substances in drinking water.

EPA and FDA agree:

(1) That contamination of drinking water from the use and application of direct and indirect additives and other substances poses a potential public health problem;

(2) That the scope of the additives problem in terms of the health significance of these contaminants in drinking water is not fully known;

(3) That the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives has been the subject of Congressional as well as public concern;

(4) That the authority to control the use and application of direct and indirect additives to and substances in drinking water should be vested in a single regulatory agency to avoid duplicative and inconsistent regulation;

(5) That EPA has been mandated by Congress under the Safe Drinking Water Act (SDWA), as amended, to assure that the public is provided with safe drinking water;

(6) That EPA has been mandated by Congress under the Toxic Substances Control Act (TSCA) to protect against unreasonable risks to health and the environment from toxic substances by requiring, *inter alia*, testing and necessary restrictions on the use, manufacture, processing, distribution, and disposal of chemical substances and mixtures;

(7) That EPA has been mandated by Congress under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to assure, *inter alia*, that when used properly, pesticides will perform their intended function without causing unreasonable adverse effects on the environment; and,

(8) That FDA has been mandated by Congress under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, to protect the public from, *inter alia*, the adulteration of food by food additives and poisonous and deleterious substances.

It is the intent of the parties that:

(1) EPA will have responsibility for direct and indirect additives to and other substances in drinking water under the SDWA, TSCA, and FIFRA; and,

(2) FDA will have responsibility for water, and substances in water, used in food and for food processing and responsibility for bottled drinking water under the FFDCA.

II. Background

(A) *FDA Legal Authority.* "Food" means articles used for food or drink for man or other animals and components of such articles. (FFDCA § 201(f)). Under Section 402, *inter alia*, a food may not contain any added poisonous or deleterious substance that may render it injurious to health, or be prepared, packed or handled under unsanitary conditions. Tolerances may be set, under Section 403, limiting the quantity of any substance which is required for the production of food or cannot be avoided in food. FDA has the authority under Section 409 to issue food additive regulations approving, with or without conditions, or denying the use of a "food additive." That term is defined in Section 201(s) to include any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, if such substance is not generally recognized as safe.

In the past, FDA has considered drinking water to be a food under Section 201(f). However, both parties have determined that the passage of the SDWA in 1974 implicitly repealed FDA's authority under the FFDCA over water used for drinking water purposes. Under the express provisions of Section 410

of the FFDCA. FDA retains authority over bottled drinking water. Furthermore, all water used in food remains a food and subject to the provisions of the FFDCA. Water used for food processing is subject to applicable provisions of FFDCA. Moreover, all substances in water used in food are added substances subject to the provisions of the FFDCA, but no substances added to a public drinking water system before the water enters a food processing establishment will be considered a food additive.

(B). *EPA Legal Authority.* The SDWA grants EPA the authority to control contaminants in drinking water which may have any adverse effect on the public health, through the establishment of maximum contaminant levels (MCLs) or treatment techniques, under Section 1412, which are applicable to owners and operators of public water systems. The expressed intent of the Act was to give EPA exclusive control over the safety of public water supplies. Public water systems may also be required by regulation to conduct monitoring for unregulated contaminants under Section 1445 and to issue public notification of such levels under Section 1414(c).

EPA's direct authority to control additives to drinking water apart from the existence of maximum contaminant levels or treatment techniques is limited to its emergency powers under Section 1431. However, Section 1442(b) of the act authorizes EPA to "collect and ake available information pertaining to esearch, investigations, and demonstrations with respect to providing a dependably safe supply of drinking water together with appropriate recommendations therewith."

TSCA gives EPA authority to regulate chemical substances, mixtures and under some circumstances, articles containing such substances or mixtures. Section 4 permits EPA to require testing of a chemical substance or mixture based on possible unreasonable risk of injury to health or the environment, or on significant or substantial human or environmental exposure while Section 8 enables EPA to require submission of data showing substantial risk of injury to health or the environment, existing health and safety studies, and other data. For new chemical substances, and significant new uses of existing chemical substances, Section 5 requires manufacturers to provide EPA with premanufacturing notice. Under Section 6 the manufacture, processing, distribution, use, and disposal of a chemical substance or mixture determined to be harmful may be restricted or banned. Although Section 3(2)(B) of TSCA excludes from the definition of "chemical substance" food and food additives as defined under FFDCA, the implicit repeal by the SDWA of FDA's authority over drinking water enables EPA to regulate direct and indirect additives to drinking water as chemical substances and mixtures under TSCA.

The FIFRA requires EPA to set restrictions on the use of pesticides to assure that when d properly, they will not cause reasonable adverse effects on the environment. EPA may require, *inter alia*, labeling which specifies how, when, and where a pesticide may be legally used. In addition, EPA has, under Section 409 of the FFDCA, required FIFRA registrants at times to obtain a food additive tolerance before using a pesticide in or around a drinking water source. Such tolerances establish further restrictions on the use of a pesticide which are enforceable against the water supplier as well as the registrant of the pesticide.

III. Terms of Agreement

(A) EPA's responsibilities are as follows:

(1) To establish appropriate regulations, and to take appropriate measures, under the SDWA and/or TSCA, and FIFRA, to control direct additives to drinking water (which encompass any substances purposely added to the water), and indirect additives (which encompass any substances which might leach from paints, coatings or other materials as an incidental result of drinking water contact), and other substances.

(2) To establish appropriate regulations under the SDWA to limit the concentrations of pesticides in drinking water; the limitations on concentrations and types of pesticides in water are presently set by EPA through tolerances under Section 409 of the FFDCA.

(3) To continue to provide technical assistance in the form of informal advisory opinions on drinking water additives under Section 1442(b) of the SDWA.

(4) To conduct and require research and monitoring and the submission of data relative to the problem of direct and indirect additives in drinking water in order to accumulate data concerning the health risks posed by the presence of these contaminants in drinking water.

(B). FDA's responsibilities are as follows:

(1) To take appropriate regulatory action under the authority of the FFDCA to control bottled drinking water and water, and substances in water, used in food and for food processing.

(2) To provide assistance to EPA to facilitate the transition of responsibilities, including:

(a) To review existing FDA approvals in order to identify their applicability to additives in drinking water.

(b) To provide a mutually agreed upon level of assistance in conducting literature searches related to toxicological decision making.

(c) To provide a senior toxicologist to help EPA devise new procedures and protocols to be used in formulating advice on direct and indirect additives to drinking water.

IV. Duration of Agreement

This Memorandum of Understanding shall continue in effect unless modified by mutual consent of both parties or terminated by either party upon thirty (30) days advance written notice to the other.

This Memorandum of Understanding will become effective on the date of the last signature.

Dated: June 13, 1979.

Douglas M. Costle,

Administrator, Environmental Protection Agency.

Dated: June 22, 1979.

Donald Kennedy,

Administrator, Food and Drug Administration.

Implementation Plan

EPA is concerned that direct and indirect additives may be adding harmful trace chemical contaminants into our Nation's drinking water during treatment, storage and distribution. Direct additives include such chemicals as chlorine, lime, alum, and coagulant aides, which are added at the water treatment plant. Although these chemicals themselves may be harmless, they may contain small amounts of harmful chemicals if their quality is not controlled. Indirect additives include those contaminants which enter drinking water through leaching, from pipes, tanks and other equipment, and their associated paints and coatings. This notice is being published in the Federal Register to solicit public comment on EPA's implementation plan to assess and control direct and indirect additives in drinking water.

Legal Authorities

EPA and the Food and Drug Administration (FDA) signed a Memorandum of Understanding which recognizes that regulatory control over direct and indirect additives in drinking water is placed in EPA. The two agencies agreed that the Safe Drinking Water Act's passage in 1974 implicitly repealed FDA's jurisdiction over drinking water as a 'food' under the Federal Food, Drug and Cosmetic Act (FFDCA). Under the agreement, EPA now retains exclusive jurisdiction over drinking water served by public water supplies, including any additives in such water. FDA retains jurisdiction over bottled drinking water under Section 410 of the FFDCA and over water (and substances in water) used in food or food processing once it enters the food processing establishment.

In implementing its new responsibilities, EPA may utilize a variety of statutory authorities, as appropriate. The authorities are identified in Appendix A.

Under the Safe Drinking Water Act, EPA has authority to set and enforce maximum contaminant levels and treatment techniques in drinking water for ubiquitous contaminants, to conduct research, to offer technical assistance to States and to protect against imminent

hazards should such situations arise. Under the Toxic Substances Control Act, EPA has authority to review all new chemicals proposed for use related to drinking water, to mandate toxicological testing of existing and new chemicals where there is evidence that such materials may pose an unreasonable risk to health and the environment as well as authority to limit some or all uses of harmful chemicals. Pesticide use is regulated by EPA under the Federal Insecticide, Fungicide and Rodenticide Act. Thus, EPA believes it has adequate authority to deal with additives to drinking water where they may pose a problem.

Past Actions

For more than ten years, the Public Health Service and other organizations which have become part of EPA have provided advisory opinions on the toxicological safety of a variety of additives to drinking water. These historical informal opinions reflect a variety of information provided by manufacturers and reflect changing toxicological concerns over the years. As such, they will require detailed review over the next few years.

General Approach

EPA intends to begin its responsibility over additives to drinking water with a series of analytical studies to determine the composition and significance of the health risks posed by contaminants related to direct and indirect additives to drinking water. A first step in this process will be monitoring studies of the contaminants actually getting into drinking water from generic categories of additives like bulk chemicals, paints and coatings, pipes and equipment.

In the initial six to twelve months, EPA will develop interim administrative procedures, testing protocols, and decision criteria for future toxicological advisories to the States. These will be distributed for public comment once they are developed. All existing opinions will remain in effect until a general review of past opinions can be undertaken using the new procedures. During this development phase, no new opinions will be rendered unless a proposed product can be shown to be virtually identical to a product for which an opinion has already been rendered, on the basis of chemical formulation and production process. New products or new uses of existing products which are proposed for use in drinking water will be subject to the pre-manufacture notice procedures of TSCA.

A more detailed outline of the steps to be taken by EPA follows.

1. *Problem Definition.*—EPA will contract for *in situ* monitoring to determine use patterns and the contribution of trace contaminants to drinking water from:

a. bulk chemicals.

b. generic classes of paints and coatings.

c. pipes and equipment.

d. coagulant aids.

EPA has already contracted with the National Academy of Sciences to develop a CODEX system of quality control standards for chemicals (direct additives) used in the treatment of drinking water. This effort will take about three years to complete. When finished, the CODEX system, modeled on the existing FDA-inspired CODEX system for chemicals used in processing food, will be largely self-enforcing.

For the indirect additives listed in items b and c above, considerable effort will be expended to identify the trace contaminants involved before the related health risks can be fully evaluated and appropriate recommendations for future use can be assessed.

2. *Review of Past Advisories.*—The same data base derived from *in situ* monitoring will serve as a basis for a structured reassessment of past toxicological advisories which will be conducted by generic classes of use e.g., paints, coagulant aides, etc. Past opinions will be reviewed to insure conformance with and satisfaction of new test protocols and decision criteria that will be developed.

3. *Future Toxicological Advisories.*—Once initial procedures, test protocols and decision criteria are developed, EPA will resume offering toxicological opinions to the States.

General Policy

In assessing additives to drinking water, EPA will be guided by a policy of reducing public health risks to the degree it is feasible to do so. In such determinations, EPA will evaluate the risks and benefits associated with the materials of concern and their substitutes. Economic impacts of agency actions will also be analyzed.

Notwithstanding these procedures, EPA would use its authorities to protect against any direct or indirect additive to drinking water when data and information indicate that the use of any additive may pose an undue risk to public health.

Implementation

To fulfill this program, resources from the Office of Drinking Water, the Office of Research and Development, and the Office of Toxic Substances will be used. In addition, EPA looks forward to the cooperation of FDA and other Federal regulatory bodies. EPA intends to involve interested industry groups, independent testing groups, State regulatory bodies, interested members of the public, and industry standards groups, in a continued effort to ensure the safety of the Nation's drinking water.

Finally, EPA may recommend specialized legislative authority to regulate additives to drinking water should a situation arise for which legal authorities prove inadequate.

Lead responsibility for this new Federal initiative will be in EPA's Office of Drinking Water. Public comments on any or all aspects of the proposed program are requested, and should be directed to the address given in the opening sections of this notice.

Dated: July 13, 1979.

Thomas C. Jorling,

Assistant Administrator for Water and Waste Management.

Appendix A

Safe Drinking Water Act

Section 1412—establishment of national primary drinking water regulations applicable to public water systems to control contaminants in drinking water which may have any adverse effect on human health. This may include maximum contaminant levels, treatment techniques, monitoring requirements, and quality control and testing procedures.

Section 1431—use of emergency powers where a contaminant which is present in water, or is likely to enter a public water system, may present an imminent and substantial endangerment to the health of persons.

Section 1445—establishment of monitoring and reporting requirements applicable to public water systems.

Section 1450—authority to prescribe such regulations as are necessary or appropriate to carry out the Administrator's functions under the Act.

Toxic Substances Control Act

Section 4—testing of chemical substances and mixtures.

Section 5—pre-manufacture notice required for new chemicals or significant new uses.

Section 6—regulation of hazardous chemical substances and mixtures which pose an unreasonable risk of injury to health or the environment, including restrictions on manufacture, processing, distribution, and use.

Section 7—imminent hazards authority including seizure and other relief through civil court action.

Section 8—reporting and retention of information as required by the Administrator, including health and safety studies and notice to the Administrator of substantial risks.

Section 10—research and development. Development of systems for storing, retrieving and disseminating data.

Section 11—inspections and subpenas and other enforcement and general administration provisions therein.

Federal Insecticide, Fungicide and Rodenticide Act

Section 3—registration of pesticides, including imposition of restrictions and labeling requirements.

Section 6—suspension and cancellation procedures.

[FR Doc. 79-22222 Filed 7-19-79; 8:45 am]

BILLING CODE 6560-01-M

BILLING CODE 4110-03-M

FEDERAL COMMUNICATIONS COMMISSION

(Report No. A-1a)

FM Broadcasting Applications Accepted for Filing and Notification of Cut-off Date; Erratum

Released: July 12, 1979.

The FM Application listed below was inadvertently included on the acceptance/cut-off notice, Report No. A-1, BC Mimeo No. 18678, released on June 25, 1979.

BPH-780108AE (New): Cresson, Pennsylvania, Sherlock-Hart Broadcasting, Inc.
Req.: 94.3 MHz, Channel #232A
ERP: 0.600 kW, HAAT: 600 feet.

Accordingly, the application is removed from the acceptance/cutoff list and the August 6, 1979, cutoff date is deleted.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 79-22422 Filed 7-19-79; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL LABOR RELATIONS AUTHORITY

Official Time of Employees Involved in Negotiating Collective Bargaining Agreements

AGENCY: Federal Labor Relations Authority.

ACTION: Notice Relating to Official Time.

SUMMARY: This notice principally relates to the interpretation of section 7131 of the Federal Service Labor-Management Relations Statute (92 Stat. 1214) on the questions of whether employees who are on official time under this section while representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses, and whether the official time provisions of section 7131(a) of the Statute encompass all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement. The notice further invites interested persons to address the impact, if any, of section 7135(a)(1) of the Statute (92 Stat. 1215) on such interpretation, and to submit written comments concerning these matters.

DATE: Written comments must be submitted by the close of business on August 24, 1979, to be considered.

ADDRESS: Send written comments to the Federal Labor Relations Authority, 1900 E Street, NW., Washington, D.C. 20424.

FOR FURTHER INFORMATION CONTACT: Harold D. Kessler, Deputy Executive Director, 1900 E Street, NW., Washington, D.C. 20424, (202) 632-3920.

SUPPLEMENTARY INFORMATION: The Federal Labor Relations Authority was established by Reorganization Plan No. 2 of 1978, effective January 1, 1979 (43 FR 36037). Since January 11, 1979, the Authority has conducted its operations under the Federal Service Labor-Management Relations Statute (92 Stat. 1191).

Upon receipt of requests and consideration thereof, the Authority has determined, in accordance with 5 CFR 2410.3(a) (1978) and sections 7105 and 7135(b) of the Statute (92 Stat. 1196, 1215), that an interpretation is warranted concerning section 7131 of the Statute (92 Stat. 1214). Interested persons are invited to express their views in writing on this matter, as more fully explained in the Authority's notice set forth below:

To Heads of Agencies, Presidents of Labor Organizations and Other Interested Persons

The Authority has received a request from the American Federation of Government Employees (AFGE) for a statement of policy and guidance concerning whether employees representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses under the official time provisions of section 7131 of the Federal Service Labor-Management Relations Statute (92 Stat. 1214). Additionally, the National Federation of Federal Employees (NFFE) has requested a major policy statement as to the application of the official time provisions of section 7131(a) of the Statute (92 Stat. 1214) to all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement. AFGE has raised a similar issue in its request.

The Authority hereby determines, in conformity with 5 CFR 2410.3(a) (1978) and section 7135(b) of the Statute (92 Stat. 1215) as well as section 7105 of the Statute (92 Stat. 1196), that an interpretation of the Statute is warranted on the following:

(1) Whether employees who are on official time under section 7131 of the Statute while representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses.

(2) Whether the official time provisions of section 7131(a) of the Statute encompass all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement.

Before issuing an interpretation on the above, the Authority, pursuant to 5 CFR 2410.8 (1978) and section 7135(b) of the Statute (92 Stat. 1215), solicits your views in writing. You are further invited to address the impact, if any, of section 7135(a)(1) of the Statute (92 Stat. 1215) on the above matters and to submit your views as to whether oral argument should be granted. To receive consideration, such views must be submitted to the Authority by the close of business on August 24, 1979.

Issued, Washington, D.C., July 13, 1979.

Federal Labor Relations Authority.

Ronald W. Haughton,

Chairman.

Henry B. Frazier III,

Member.

[FR Doc. 79-22449 Filed 7-19-79; 8:45 am]

BILLING CODE 6325-01-M

APPENDIX D

53 FR 25586-01, 1988 WL 260340 (F.R.)

NOTICES

ENVIRONMENTAL PROTECTION AGENCY

[OW-FRL-3410-1]

Drinking Water Technical Assistance; Termination of the Federal Drinking Water Additives Program

Thursday, July 7, 1988

*25586 AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA), Office of Drinking Water (ODW), has operated an advisory program that gives technical assistance to concerned parties on the use of drinking water additives. On May 17, 1984, EPA proposed to terminate major elements of this Federal program and to assist in the establishment of a private-sector program which would offer assistance in evaluating drinking water additives. 49 FR 21004. EPA solicited proposals from qualified nongovernmental, nonprofit organizations for assistance under a cooperative agreement to establish a credible and efficient program in the private sector.

On September 17, 1985, EPA selected a consortium consisting of the National Sanitation Foundation (NSF), the American Water Works Association Research Foundation (AWWARF), the Conference of State Health and Environmental Managers (COSHEM), and the Association of State Drinking Water Administrators (ASDWA) to receive funds under a cooperative agreement to develop the private-sector program. EPA believes that the NSF-led program has proceeded satisfactorily. NSF Standard 60, covering many direct additives, was adopted on December 7, 1987; and NSF Standard 61, covering indirect additives, was adopted on June 3, 1988. Other standards are forthcoming. The NSF-led program has begun offering testing, certification, and listing services, as described in 49 FR 21004, for certain classes of products covered by these standards. Accordingly, as the NSF-led program becomes operational, EPA will phase out its activities in this area, as described in this notice.

DATE: Any written comments on implementing this notice should be submitted to the address below by September 6, 1988.

ADDRESSES: Submit comments to: Mr. Arthur H. Perler, Chief, Science and Technology Branch, Office of Drinking Water (WH-550D), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. A copy of all comments will be available for review during normal business hours at the U.S. Environmental Protection Agency, Criteria and Standards Division, Science and Technology Branch, Room 931ET, 401 M Street, SW., Washington, DC 20460. For further information on the NSF-led private-sector program, including standards development and testing, certification, and listing services, contact: Director, Drinking Water Additives Program, National Sanitation Foundation, P.O. Box 1468, Ann Arbor, MI 48106; or call (313) 769-8010. For information on alternative testing, certification, and listing programs, contact individual State regulatory authorities or the American Water Works Association, Technical and Professional Department, 6666 Quincy Avenue, Denver CO, 80235, or call (303) 794-7711. For information on the directory of products certified as meeting the criteria in a NSF standard, contact the American Water Works Association Research Foundation, 6666

Quincy Avenue, Denver CO, 80235, or call (303) 794-7711.

FOR FURTHER INFORMATION CONTACT:Mr. Arthur H. Perler, Chief, Science and Technology Branch, Office of Drinking Water (WH-550D), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, or call (202) 382-2022.

I. Introduction

The Safe Drinking Water Act (SDWA) (42 U.S.C. 300f et seq.) provides for enhancement of the safety of public drinking water supplies through the establishment and enforcement of national drinking water regulations. The Environmental Protection Agency (EPA) has the primary responsibility for establishing the regulations, and the States have the primary responsibility for enforcing such regulations. The regulations control contaminants in drinking water which may have any adverse effect on public health. Section 1412, 42 U.S.C. 300g-1. The regulations include maximum contaminant levels (MCLs) or treatment techniques and monitoring requirements for these contaminants. Sections 1401 and 1412; 42 U.S.C. 300f and 300g-1. EPA also promulgates monitoring requirements for unregulated contaminants. Section 1445; 42 U.S.C. 300j-4. In addition, EPA has broad authorities to provide technical assistance and financial assistance (e.g., grants, cooperative agreements) to States and to conduct research. Sections 1442, 1443, 1444; 42 U.S.C. 300j-1, 300j-2, 300j-3.

The Agency has established MCLs for a number of harmful contaminants that occur naturally or pollute public drinking water supplies. In addition to such contaminants, there is a possibility that drinking water supplies may be contaminated by compounds "added" to drinking water, either directly or indirectly, in the course of treatment and transport of drinking water. Public water systems use a broad range of chemical products to treat water supplies and to maintain storage and distribution systems. For instance, systems may directly add chemicals such as chlorine, alum, lime, and coagulant aids in the process of treating water to make it suitable for public consumption. These are known as "direct additives." In addition, as a necessary function of maintaining a public water system, storage and distribution systems (including pipes, tanks, and other equipment) may be fabricated from or painted, coated, or treated with products which may leach into or otherwise enter the water. These products are known as "indirect additives." Except to the extent that direct or indirect additives consist of ingredients or contain contaminants for which EPA has promulgated MCLs, EPA does not currently regulate the levels of additives in drinking water.

In 1979, EPA executed a Memorandum of Understanding (MOU) with the U.S. Food and Drug Administration (FDA) to establish and clarify areas of authorities with respect to control of additives in drinking water. 44 FR 42775, July 20, 1979. FDA is authorized to regulate "food additives" pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA). (21 U.S.C. 301 et seq.). Both agencies acknowledged in the MOU that "passage of the SDWA in 1974 repealed FDA's authority under the FFDCA over water used for drinking water purposes."The MOU stated that FDA would continue to have authority for taking regulatory action under the FFDCA to control additives in bottled drinking water and in water used in food and for food processing. The MOU went on to say that EPA had authority to control additives in public drinking water supplies.

While the SDWA does not require EPA to control the use of specific additives in drinking water, EPA has provided technical assistance to States and public water systems on the use of additives through the issuance of advisory opinions on the acceptability of many additive products. EPA has provided this technical assistance pursuant to its discretionary authority in section 1442(b)(1) to "collect and make available information pertaining to research, investigations and demonstrations with respect to *25587 providing a dependable safe supply of

drinking water together with appropriate recommendations in connection therewith."EPA has additional authorities under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 .et seq.) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 et seq.) that could be used to control additives in drinking water. TSCA authorizes EPA to regulate a new chemical substance before it is manufactured or any existing chemical substance before it is manufactured or processed for a use that EPA has determined to be a "significant new use." Although an additive product might come within the jurisdiction of TSCA, EPA has never invoked this authority. EPA has used its authority under FIFRA to control the use of pesticides, disinfectants, and certain other additives. For a more complete discussion of these authorities, see the MOU. 44 FR 42776.

In 1980, EPA declared a moratorium on the issuance of new advisory opinions on additives pending a review of past advisory opinions and the establishment of uniform test protocols and decision criteria. However, between 1980 and 1984, EPA continued to issue advisory opinions in cases where the new additive products were virtually identical to products previously reviewed. Resource constraints and the need to implement mandatory provisions of the SDWA precluded the Agency from implementing the comprehensive program originally envisioned for the issuance of additives advisory opinions. Thus, the Agency was not able to review the technical data supporting previous submissions (approximately 2,300 products from 525 manufacturers) nor was it able to develop test protocols or decision criteria for the consistent evaluation of new products. The result has been long delays in processing manufacturer petitions, inability to review and accept completely new products, and acceptance of products simply because they were virtually identical to older products. Hence, few products have been thoroughly evaluated for the safety of their formulations based on the latest scientific information.

Recognizing the need for continuing technical assistance in evaluating additive products and for providing advice to States and public water systems on the toxicological aspects of additive products, the Agency proposed to terminate its attempts to institute a formal advisory program, and to solicit proposals from nongovernmental, nonprofit organizations to establish such a program in the private sector. The Agency believed that the proposal to assist in the establishment of a private-sector program was consistent with, and would best serve the goals of, the SDWA.

On May 17, 1984, EPA formally announced its intention to transfer the program to the private sector, which would function as to many other voluntary product-standard programs. 49 FR 21004. This was accomplished by requesting proposals from qualified organizations or consortia of organizations for the competitive award of a cooperative agreement designed to provide incentive for the establishment of a private-sector program. The 1984 notice stated that:

- EPA expected the activity to be self-supporting.

- EPA would maintain an active interest in the development of the program, without assuming responsibility for or directing its approach.

- EPA would continue to establish regulations under the SDWA, FIFRA, and/or TSCA, as needed, for chemicals in treated, distributed drinking water that may originate as additives.

- Establishment of such a program would be consistent with the Administration's initiatives in the area of regulatory reform and offered an opportunity for an innovative alternative to regulation.

The May 1984 notice requested public comments on the proposal and solicited applications from qualified nongovernmental, nonprofit organizations for partial funding of the developmental phase of the program under a co-

operative agreement. The response to the solicitation for comments indicated strong public support for the proposed approach. EPA received 106 public comments on the proposal. All but six supported this "third-party" approach. However, despite the Agency's open competition, EPA received only one application for financial assistance. The applicant was a consortium, led by the National Sanitation Foundation, which included the American Water Works Association Research Foundation, the Conference of State Health and Environmental Managers, and the Association of State Drinking Water Administrators. This single proposal met all of the basic criteria articulated in the May 1984 notice. Furthermore, EPA believed that the single applicant was very likely to succeed, because it represented an organization experienced in private-sector consensus standard-setting, State regulators, and water utilities.

EPA awarded the cooperative agreement to the NSF consortium on September 17, 1985, and committed funding of $185,000 to NSF over a three-year period. The non-Federal (consortium and participating industry) contribution during the first three years of the program was projected to be approximately $1.4 million.

The NSF program has the following major objectives:

- To develop systematic, consistent, and comprehensive voluntary consensus standards for public health safety evaluation of all products (previously EPA-accepted as well as new) intended for use in drinking water systems.

- To obtain broad-based participation in the standard-setting program from industry, States, and utilities.

- To provide for regular periodic review, update, and revision of the standards.

- To undertake needed research, testing, evaluation, and inspections and to provide the followup necessary to maintain the program.

- To establish a separate program for testing, evaluation, certification, and listing of additive products.

- To widely disseminate information about the program, and to make information about conforming products available to users.

- To maintain the confidentiality of all proprietary information.

- To fully establish the third-party program on a self-supporting basis.

NSF's established standard-setting process utilizes a tiered structure. Each standard is drafted by a task group and then presented to a Joint Committee, which includes 12 industry, 12 user, and 12 regulatory members. Following successful Joint Committee balloting, standards are reviewed by the Council of Public Health Consultants, which is a high level advisory group consisting of technical and policy experts from regulatory agencies and academia.

NSF has established task groups to develop standards for the product categories listed below. Each task group includes a member representing the regulatory agencies and a member representing the utilities. All manufacturers expressing interest in a particular product task group may participate as members of that group. Therefore, task group membership is predominately manufacturers. In addition, a group of health effects consultants is addressing the toxicological and risk considerations for various product categories. NSF's role in the standard-setting process is administrative, that is, to bring together experts from government, industry, ***25588** utilities, users, and other relevant groups so that a standard which reflects a consensus of these interests can be de-

veloped. In addition, NSF staff provide technical leadership and laboratory support. Product categories and corresponding task groups are:

- Protective Materials.

- Chemicals for Corrosion and Scale Control, Softening, Precipitation, Sequestering, and pH Adjustment.

- Coagulation and Flocculation Chemicals.

- Miscellaneous Treatment Chemicals.

- Joining and Sealing materials.

- Process Media.

- Pipes and Related Products.

- Disinfection and Oxidation Chemicals.

- Mechanical Devices.

All of the task groups have made satisfactory progress during the term of the cooperative agreement. In addition, the health effects consultants have endorsed the bases of the standards. Standards have been drafted for all product categories, and final standards were published and implemented as follows:

Standard 60, December 1987

- Chemicals for Corrosion and Scale Control, Softening, Precipitation, Sequestering, and pH Adjustment.

- Disinfection and Oxidation Chemicals.

- Miscellaneous Treatment Chemicals (selected).

Standard 61, June 1988

- Process Media.

Development of the remaining standards is on schedule, and publication and implementation are expected on the following schedule:

Standards 60 and 61, expected October 1988

- Protective Materials.

- Coagulation and Flocculation Chemicals.

- Miscellaneous Treatment Chemicals (additional).

- Joining and Sealing Materials.

- Pipes and Related Products.

- Mechanical Devices.

EPA believes that the NSF program is successfully pursuing all of its objectives. Furthermore, the program is strongly supported by user and regulatory sectors. AWWARF, COSHEM, ASDWA, the Great Lakes Upper Mississippi River Board, the American Water Works Association (AWWA) (including the Utilities and Standards Councils and the Regulatory Agencies Division), and the Association of Metropolitan Water Agencies, among others, have voiced strong support for the third-party program. The AWWA recently joined the NSF-led consortium and urged EPA to support national uniform accreditation of certifying entities for additives products. To date, more than 60 manufacturers are full participants in the standard-setting program.

The cooperative agreement between EPA and the consortium requires NSF to establish both a standard-setting program and a service for testing, certification, and listing. These are completely separate activities. EPA's intent is to support the development of a widely accepted uniform standard for each category of products while encouraging the development of competing sources for testing, certification, and listing. The cooperative agreement assures that at least one sound and reliable product-evaluation service will be available to manufacturers, i.e., the consortium. However, the consortium's standards will allow for entities other than NSF to be evaluators of products.

EPA recognizes the authority and responsibility of the individual States to determine the acceptability of drinking water additives. Hence, it is up to the States and utilities to determine the suitability of any "third-party" certification. AWWARF will maintain a directory of products approved by all organizations claiming to conduct evaluations under Standards 60 and 61. However, AWWARF will not judge the competence or reliability of these organizations.

II. Announcement of Phase-Down of EPA's Additives Program

During the developmental phase of the NSF consortium's program, EPA has continued to review products and process requests for advisory opinions on a limited basis. The May 1984 notice stated that, "EPA does not intend to develop further interim administrative procedures, testing protocols or decision criteria for future evaluation of additive products. The use of existing informal criteria will continue until a third-party or alternative program is operational * * *. EPA may not be able to process all requests for opinions on additive products before the establishment of a cooperative agreement with a third party. The large volume of currently pending requests makes it unlikely that additional requests will be completely processed by that date."Likewise, EPA, in its acknowledgment letters to manufacturers requesting opinions on new products, explains that the Agency is, "* * * making a concerted effort to process petitions as quickly as possible. However, EPA may not be able to process your request for an opinion on an additive product before the establishment of an alternative program as described in the Federal Register, Vol. 49, No. 97, 21003-8, May 17, 1984."Product reviews and issuance of advisory opinions have been limited to:

- Products composed entirely of other products which EPA had previously determined to be acceptable;

- Products composed entirely of ingredients which have been determined to be acceptable by EPA or the FDA, or other Federal agencies, for addition to potable water or aqueous foods;

- Products composed entirely of ingredients listed in the "Water Chemicals Codex," National Academy of Sciences, November 1982, and in the "Water Chemicals Codex: Supplementary Recommendations for Direct Additives," National Academy of Sciences, 1984;

- Certain other products of particular interest to EPA or to other Federal agencies; and

- Products which, if effectively excluded from the marketplace by lack of approval, might jeopardize public health or safety.

Continued processing of petitions during the development of the private-sector program minimized disruption of the marketplace from the viewpoint of manufacturers whose business depended in part on EPA acceptance of products, users who required water treatment products for the production of safe drinking water, and State officials who rely on the advice of EPA.

EPA believes that NSF is moving expeditiously and on schedule toward the full establishment of a third-party program covering products intended for use in drinking water systems. Priorities for standards development and implementation of a testing, certification, and listing program for various product categories have been based upon need, interest, complexity, and availability of information for developing standards. Direct drinking water additives were assigned high priority for the following reasons: (1) Use of direct additives is widespread in drinking water systems, so there are large population exposures to these chemicals; (2) as direct additives to drinking water, they present greater potential for water contamination than indirect mechanisms (e.g., migration from protective paints in pipes and storage tanks); and (3) the National Academy of Sciences' Water Chemicals Codex provided a good starting point for development of standards.

*25589 As originally planned, EPA is beginning to phase out the Agency's additives evaluation program. Thus, EPA will not accept new petitions or requests for advisory options after the date of this notice. While EPA will continue to process requests which are pending and those received on or before July 7, 1988, petition evaluations not completed by October 4, 1988, will be returned to the submitter. After that date, EPA will no longer evaluate additive products.

Petitions which are completely evaluated by October 5, 1988, will be added to the quarterly list of acceptable products published shortly after that date. That quarterly list will be the last such list issued by EPA. On April 7, 1990, EPA will withdraw its list of acceptable products, and the list and the advisories on these additives will expire. This means that: (1) The various lists published by EPA under the titles Report on Acceptable Drinking Water Additives, Report on Coagulant Aids for Water Treatment, Report on Concrete Coatings/Admixture for Water Treatment, Report on Detergents, Sanitizers and Joint Lubricants for Water Treatment, Report on Evaporative Suppressants for Water Treatment, Report on Liners/Grouts/Hoses and Tubings for Water Treatment, Report on Miscellaneous Chemicals for Water Treatment, Report on Protectivce Paints/Coatings for Water Treatment, and any and all other lists of drinking water products issued by EPA or its predecessor agencies regarding drinking water additives will be invalid after April 7, 1990; and (2) advisory opinions on drinking water additives issued by EPA and predecessor agencies will be invalid after that date.

EPA believes that, while in the past every effort has been made to provide the best possible evaluations, all products should be evaluated against carefully developed and considered nationally uniform standards. Many of the currently listed products were evaluated and accepted up to 20 years ago and have not been reevaluated since that time. Numerous products have been accepted because they were virtually identical to or were repackagings of older products. The result is that few products have been completely evaluated for the safety of their original or current formulations vis-a-vis the latest toxicological, chemical, and engineering information. A uniform evaluation of all products, old and new, will result in consistent quality of products, and will assure fair and equitable treatment to all manufacturers and distributors.

Henceforth, parties desiring to have existing or new products evaluated against the NSF standards should contact NSF or other organizations offering such evaluations. To contact NSF about the drinking water additives program write to: David Gregorka, National Sanitation Foundation, P.O. Box 1468, Ann Arbor, MI 48106, or call (313) 769-8010. Information on alternatives to NSF evaluation may be obtained by contacting State regulatory agencies or the AWWA, Technical and Professional Department, 6666 Quincy Avenue, Denver Co, 80235, or call (303) 794-7711, which is addressing certifier accreditation.

EPA believes that the 21 months between today and the expiration date of EPA's last list is sufficient time for manufacturers to submit their products to NSF or other certification entities for evaluation. The first NSF list will be published prior to April 7, 1990, thereby preventing any disruption in the marketplace. Furthermore, NSF had indicated that it will consider current EPA and other regulatory evaluations when evaluating products in order to ensure a smooth transition. States may choose to rely on the last EPA quarterly list of products until their individual programs for accepting private-sector certification are fully implemented.

Parties desiring to market drinking water additive products are reminded that the individual States have the authority to regulate the sale and/or use of specific products as they see fit. Thus, reliance upon a particular standard or organization to certify that a product complies with a particular standard must be acceptable to the State in which the supplier wishes to do business.

Discontinuation of the additives program at EPA does not relieve the Agency of its statutory responsibilities. If contamination resulting from third-party sanctioned products occurs or seems likely, EPA will address that issue with appropriate drinking water regulations or other actions authorized under the SDWA. EPA is a permanent member of the NSF program Steering Committee, and senior EPA staff and management will continue to participate in this and other programs designed to assure that high-quality products are employed in the treatment of public drinking water. Also, the Agency will continue to sponsor research on contaminants introduced in public water supplies during water treatment, storage, and distribution.

III. Comments

Although this notice does not include a proposed or final regulation, EPA welcomes comments and suggestions that would assist the Agency in implementing the additives program phasedown. Please address all comments and suggestions to: Mr. Arthur H. Perler, Chief, Science and Technology Branch, Office of Drinking Water (WH-550D), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Date: June 16, 1988.

William Whittington,

Acting Assistant Administrator for Water.

[FR Doc. 88-15232 Filed 7-6-88; 8:45 am]

BILLING CODE 6560-50-M

53 FR 25586-01, 1988 WL 260340 (F.R.)
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APPENDIX E

RULES and REGULATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 103

(Docket No. 89N-0469)

Quality Standards for Foods With No Identity Standards; Bottled Water

Tuesday, January 5, 1993

*378 AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the quality standards for bottled water by establishing allowable levels for the following seven synthetic volatile organic chemicals (VOC's): Benzene (not to exceed 0.005 milligrams per liter(mg/L); carbon tetrachloride (not to exceed 0.005 mg/L); 1,2-dichloroethane (not to exceed 0.005 mg/L); 1,1-dichloroethylene (not to exceed 0.007 mg/L); 1,1,1-trichloroethane (not to exceed 0.20 mg/L); trichloroethylene (TCE) (not to exceed 0.005 mg/L); and vinyl chloride (not to exceed 0.002 mg/L). FDA is taking this action to amend the quality standard for bottled water following rulemaking by the Environmental Protection Agency (EPA) that established maximum contaminant levels (MCL's) for these seven compounds in public drinking water. This rulemaking will ensure that the minimum quality of bottled water remains comparable with the quality of public drinking water meeting EPA standards.

DATES: Effective July 6, 1993. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 103.35(d)(3), effective July 6, 1993.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5229.

SUPPLEMENTARY INFORMATION:

I. Background

Section 410 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 349) requires that whenever EPA prescribes interim or revised National Primary Drinking Water Regulations (NPDWR's) under the Safe Drinking Water Act (SDWA), FDA consult with EPA and either amend its regulations for bottled drinking water (21 CFR 103.35) or publish in the Federal Register its reasons for not making such amendments.

In the Federal Register of July 8, 1987 (52 FR 25690), EPA issued a final rule establishing NPDWR's consisting of MCL's for eight VOC's. In accordance with section 410 of the act, FDA published a proposal in the Federal Register of July 6, 1990 (55 FR 27831) announcing the agency's intent to adopt the MCL's of EPA as quality standards for seven of the VOC's addressed in EPA's final rule, as follows: benzene—0.005 mg/L; carbon tetrachloride—0.005 mg/L; 1,2-dichloroethane—0.005 mg/L; 1,1-dichloroethylene—0.007 mg/L; 1,1,1-trichloroethane—0.20 mg/L; trichloroethylene—0.005 mg/L; and vinyl chloride—0.002 mg/L. FDA summarized the toxicological evidence relied upon by EPA for each of the seven VOC's in establishing MCL's (55 FR 27831 and 27832) and discussed the reasons for the agency's tentative determination to adopt the MCL's as the allowable levels for these chemical contaminants in bottled water (55 FR 27832 through 27833). FDA did not propose to adopt an allowable level for the eighth VOC covered by EPA's proposal, para-dichlorobenzene (p-dichlorobenzene), because EPA was in the midst of a second rulemaking on this chemical contaminant, and FDA felt that it was appropriate to postpone action with respect to this substance (55 FR 27831).

Following publication of this proposal, FDA reopened the 60-day comment period for an additional 30 days by a notice published in the Federal Register of March 21, 1991 (56 FR 11979). That notice announced that: (1) The enactment on November 8, 1990, of the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) removed the rulemaking procedures for quality standards for foods from the formal rulemaking provision of section 701(e) of the act (21 U.S.C. 371(e)), and (2) FDA was therefore redesignating the VOC rulemaking as a notice and comment rulemaking that would proceed under the provisions of section 701(a) of the act (21 U.S.C. 371(a)). As a result of the change announced by FDA on March 21, 1991, and in the interest of fairness, the comment period was reopened to provide an additional opportunity for public comment because the 701(a) procedures do not provide an opportunity to submit objections to the final rule as do the formal rulemaking provisions under which this action was initiated.

II. Summary of and Response to Comments

A. Summary of Comments

FDA received 13 comments in response to the July 6, 1990, proposal. The comments represented the views of a foreign government's office for General Agreement for Tariffs and Trade (GATT) Enquiry Point, a chemical supply company, three State water districts, a consortium of State water districts, four trade associations representing the interests of both public water and bottled water providers, a State health department, a bulk water company, and one individual. Eleven of the 13 comments agreed that FDA should adopt the proposed VOC levels based on EPA requirements for public drinking water and the public's expectation that bottled water should at least meet the standards set by EPA for public drinking water.

The comment from the foreign GATT Enquiry Point stated that their country had not set contaminant level standards for VOC's because they believe VOC contaminants are unacceptable in bottled water. The remaining comment, while concurring that FDA should consider MCL's when adopting quality standards, stated that FDA should establish maximum VOC levels on the basis of its own toxicological assessment of appropriate and permissible levels of contaminants in drinking water.

B. Response to Comments

1. In response to the foreign government's comment objecting to the acceptability of VOC contaminants in bottled water, the agency notes that FDA and EPA recognize that in certain instances, the presence of VOC's and other undesirable substances in drinking water sources may be unavoidable. These substances are widely dispersed in the environment and have been found in some public and bottled water sources. The legally prescribed course of action under the SDWA and the act with respect to such contaminants is for EPA to establish limits for them that provide for the protection of the public health and, when appropriate, for FDA to adopt limits for these contaminants in bot-

tled water. It has been FDA's policy to fulfill its legal obligation under the act by amending the quality standard for bottled water to include allowable limits for contaminants that EPA has regulated under the SDWA.

Acceptable, health-based limits for such substances in public drinking water are set by EPA by determining a lifetime exposure level at which no known or anticipated adverse health *379 effects occur and that will provide an adequate margin of safety. EPA uses these criteria to establish maximum contaminant level goals (MCLG's) and then sets the MCL's as close as feasible to the MCLG's.

Under the SDWA, "feasible" means possible with the use of the best technology, treatment techniques, and other means that are found to be practical under actual field conditions for removal or reduction of the contaminant to a level that protects the public health (52 FR 25690 at 25097). For example, EPA set the MCL's for the carcinogenic VOC's addressed in this rulemaking (0.002 mg/L for vinyl chloride and 0.005 mg/L for benzene, carbon tetrachloride, 1,1-dichloroethane, and trichloroethylene) as close as is feasible to the MCLG's of zero, that is, at the practical quantitation limits (PQL's) of the analytical methods used to measure each of these contaminants (52 FR 25690 at 25700).

Given these considerations, FDA believes that the MCL's for these seven VOC's are appropriate as maximum allowable levels for these contaminants in bottled drinking water. By adopting limits on these VOC's, FDA is not condoning their presence in bottled water, as implied by the comment, but is instead acting to protect the public by limiting potentially harmful levels of exposure to these contaminants that may occur.

2. The comment that suggested that FDA should conduct its own assessment of drinking water contaminant levels argued that such an assessment was especially important because the MCLG's set by EPA for the substances that are the subject of this rulemaking were based on EPA policy and not on the science at issue. This comment questioned the scientific basis upon which EPA assigned MCLG's of zero to all carcinogens which EPA categorized as Group B (Probable Human), because B2 substances, that is, substances that have been shown to be carcinogens in animal testing but for which there is no evidence of human cancer risk, should not be assigned MCLG's of zero. In particular, the comment contended, and provided documents to support its contention, that TCE was misclassified by EPA as a B2-probable human carcinogen. The comment concluded that FDA should review the scientific basis for EPA's drinking water standards and reevaluate the proposed bottled water quality standard for TCE, considering that it should be classified as a Group C-possible human carcinogen.

To avoid any misunderstanding, FDA notes that it does not have authority to set standards for public drinking water. Under the provisions of the SDWA of 1974, EPA is charged with ensuring that the public is provided with safe drinking water and with establishing standards for contaminants (as MCL's) in public drinking water sources. FDA, under a memorandum of understanding between EPA and FDA (44 FR 42775, July 20, 1979), is responsible for water, and substances in water, used in food and for food processing and for bottled drinking water.

In the case of bottled water, it has been FDA's policy to fulfill its charge under section 410 of the act by adopting EPA drinking water standards as maximum allowable levels for contaminants in bottled water unless there exist reasons for FDA to conclude that certain EPA standards are not applicable to bottled water. For example, an EPA standard for drinking water may be inappropriate as an allowable level for a contaminant in bottled water if it is reasonable to expect that lower levels of the contaminant will be present in bottled water because the presence of the contaminant in drinking water is the result of circumstances peculiar to public water systems that can be avoided by bottlers, e.g., lead in pipes, solder, or brass fittings.

As explained in the July 6, 1990, proposal, FDA tentatively decided to adopt the EPA's health-based MCL's for seven of the eight VOC's under section 410 of the act because some sources for bottled drinking water may be expected to contain these VOC contaminants. In addition, the agency noted that in some cases bottled water may be consumed daily in amounts similar to the consumption of water from public water supplies. In cases where bottled

water is subject to the same source contaminants as public water supplies, FDA believes that to ensure the quality of bottled water, the allowable levels for contaminants should normally correspond to the levels set by EPA as the MCL's for public water supplies. FDA proposals that respond to EPA rulemaking under the SDWA generally have not duplicated the efforts of EPA in judging the adequacy of NPDWR's for the protection of the public health. In most cases, (except as noted in the previous paragraph) FDA will propose to adopt EPA's MCL's as quality standards for bottled water.

It would clearly be inappropriate for FDA to reevaluate or revise the drinking water standards duly prescribed by another Federal agency. For FDA to reexamine, as suggested in the comment, the full scope of the toxicological issues for each contaminant after EPA has done so, and after EPA has established MCL's under notice and comment rulemaking procedures, would be redundant and inconsistent with the intent of section 410 of the act.

However, before proposing to adopt the MCL's for the seven VOC's, FDA did in fact review the overall results of the toxicological studies conducted with the VOC's. As a result, FDA found that it agreed completely with EPA's conclusions. These conclusions were, in part, based on studies showing that TCE causes liver tumors in mice when administered orally at high doses over the lifetime of the animals. Considering these data and the possible chronic human exposure to this contaminant from daily water consumption, FDA believes that EPA's MCL for TCE is a reasonable health-based drinking water contaminant level limit. Therefore, FDA rejects the comment's suggestion that it conduct its own assessment of drinking water contaminant levels for bottled water and reevaluate the carcinogenic potential of TCE in humans and is adopting the 0.005 mg/L MCL for TCE as the allowable level for this substance in the quality standard for bottled water.

However, should new data or a reexamination of the toxicological status of TCE lead EPA to conclude that TCE is not a potential human carcinogen, or that it has otherwise misclassified this substance, FDA will consider amending the bottled water quality standards to reflect any significant revision in the MCL by EPA.

3. The comments received from trade associations and State water officials uniformly urged that FDA adopt the VOC standards as proposed and stressed a need for more stringent regulation of the bottled water industry. The comments called for more frequent inspections and analyses of water samples, better coordination of recalls, labeling on bottled water products that identifies the source and purity of the water, a national registry for bottled waters, the use of only certified State or Federal testing laboratories for required water analyses, and limits for other organic and inorganic contaminants. One comment encouraged FDA to define the terms used in the labeling of bottled water, to adopt a program to provide guidance to States for approving and protecting bottled water sources, and to develop a regular testing and monitoring program to be funded by user fees based on production volume.

Other comments from State water officials cited recent experiences with bottled waters found to contain chlorodifluoromethane (a Freon), xylene, toluene, and lead contaminants and suggested that FDA regulate the *380 levels of these compounds in bottled water. These comments requested that FDA eliminate the current exemption for bottled mineral waters from compliance with the quality standard for bottled water, citing recent experience with contaminated mineral waters and noting that mineral water sources are subject to some of the same contaminants as are other bottled water sources. All of these comments requested that FDA adopt the MCL for p-dichlorobenzene. As noted above, FDA stated in the July 6, 1990, proposal that it would delay adoption of the allowable level of this chemical until EPA completes rulemaking on the secondary MCL that it proposed for this chemical on May 22, 1989 (54 FR 22062). EPA has since stated (56 FR 3526, January 30, 1991) that it is deferring promulgation of a secondary MCL for p-dichlorobenzene.

Most of the issues raised in these comments are outside the scope of this rulemaking, which addresses only the adoption of the quality standards for seven VOC's. It is inappropriate for FDA to respond here to issues that were not raised by the proposal. However, many of the concerns expressed in the comments either are the subject of separate rulemakings by the agency in response to EPA's promulgation of NPDWR's for 38 contaminants in drinking water, including toluene, xylenes, and p-dichlorobenzene (56 FR 3526, January 30, 1991 and 56 FR 30266, July 1,

1991), to EPA's promulgation of NPDWR's for lead and copper in drinking water (56 FR 26460, June 7, 1991) , or to a petition filed by the International Bottled Water Association (IBWA) (see proposals published elsewhere in this issue of the Federal Register).

Revision of the agency's required frequency of testing for contaminants in bottled water, as advocated in the comments received from trade associations and State water officials, while not the subject of this rulemaking, was discussed in the proposal in relation to the required minimum annual testing for chemical contaminants in the source water and in bottled water products under the provisions of current good manufacturing practice (CGMP) regulations (21 CFR 129.35). FDA continues to believe that it is not necessary to revise the frequency requirements for the analysis of bottled water at this time. In particular, the agency reminds bottlers that they are responsible for ensuring, through appropriate manufacturing techniques and sufficient quality control procedures, that all bottled water products introduced or delivered for introduction into interstate commerce comply with the quality standard set forth in § 103.35. Bottled water that does not comply with a requirement in § 103.35 must bear a label statement that the water is of substandard quality (§ 103.35(f)). Moreover, any bottled water that contains a substance that presents a health concern may be subject to regulatory action under section 402(a)(1) of the act, even if the bottled water bears a label statement of substandard quality (§ 103.35(g)).

III. Conclusions

EPA's drinking water regulations promulgated under the SDWA are extensive and address several distinct types of chemical contaminants in drinking water. To facilitate the understanding and use of § 103.35 after FDA makes the anticipated extensive amendments to this regulation in response to EPA rulemakings, FDA has reorganized § 103.35(d) (the paragraph of the bottled water quality standard that contains allowable levels for individual chemical contaminants) by listing levels for chemical contaminants established pursuant to section 410 of the act in new paragraph (d)(3), which is divided to reflect the different categories of chemical contaminants addressed by EPA in its regulations. Specifically, paragraph (d)(3) contains: (1) The allowable levels for inorganic contaminants in § 103.35(d)(3)(i); (2) the allowable levels for VOC's in paragraph (d)(3)(ii); (3) the allowable levels for pesticides and other synthetic organic chemicals in paragraph (d)(3)(iii); and (4) the allowable levels for chemicals for which EPA has established secondary maximum contaminant levels in paragraph (d)(3)(iv). In addition, § 103.35(d)(3)(vi) contains provisions concerning analytical methodology to be used in determining compliance with the allowable levels.

Because this reorganization of § 103.35(d) is not a substantive change, under 5 U.S.C. 553(b) and 21 CFR 10.40(d), FDA finds that rulemaking is unnecessary. FDA is codifying the provisions of this final rule in the reorganized format for § 103.35(d). Specifically, FDA is listing the maximum allowable levels for the seven VOC's in bottled water in § 103.35(d)(3)(ii) and the methodologies for analyzing for these contaminants in § 103.35(d)(3)(vi). Furthermore, at this time, FDA is reserving sections of § 103.35(d)(3) that will list the allowable levels and appropriate methods for chemical contaminants other than VOC's (e.g., inorganic chemicals, pesticides, and synthetic organic chemicals).

Therefore, upon the effective date of this rule, July 6, 1993, any bottled water that contains an amount of any of these contaminants that exceeds the allowable levels will be misbranded under section 403(h)(1) of the act (21 U.S.C. 343(h)(1)) unless it bears a statement of substandard quality as provided by § 103.35(f)(2)(ii).

FDA has made two minor changes in the final rule concerning the analytical methods for the determination of the seven VOC's. First, the § 103.35(d)(3)(vi) of the final rule cites an updated version of the EPA publication that contains the analytical methods ("Methods for the Determination of Organic Compounds in Drinking Water," Office of Research and Development, Environmental Monitoring Systems Laboratory, EPA/600/4-88/039, December 1988) that are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Second, the source for these methods will be the National Technical Information Service rather than FDA. This change is consistent with the agency's practice of relying on readily available commercial sources for incorporated materials when possible.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (55 FR 27831, July 6, 1990). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Economic Impact

FDA has examined the economic implications of this final rule to amend 21 CFR part 103 as required by Executive Orders 12291 and 12612 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12291 compels agencies to use a cost-benefit analysis as a component of decisionmaking, and Executive Order 12612 requires Federal agencies to ensure that Federal solutions, rather than State or local solutions, are necessary. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. FDA has received no new information or comments that would alter its tentative finding in the proposal that there is no substantive economic issue, and that this rule is not a major rule as defined by either Executive Order 12291 or the Regulatory Flexibility Act. Finally, because this regulation applies to food *381 for interstate trade, and individual State regulations would hinder interstate trade, FDA finds that there is no substantial Federalism issue that would require an analysis under Executive Order 12612.

List of Subjects in 21 CFR Part 103

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 103 is amended as follows:

PART 103—QUALITY STANDARDS FOR FOODS WITH NO IDENTITY STANDARDS1. The authority citation for 21 CFR part 103 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 410, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 349, 371, 376).

21 CFR § 103.35

2. Section 103.35 is amended by adding new paragraph (d)(3) to read as follows:

21 CFR § 103.35

§ 103.35 Bottled water.

* * * * *

(d) * * *

(3) Having consulted with the U.S. Environmental Protection Agency (EPA) as required by section 410 of the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration has determined that bottled water, when a composite of analytical units of equal volume from a sample is examined by the methods listed in paragraph (d)(3)(vi) of this section, shall not contain the following chemical contaminants in excess of the concentrations

specified in paragraph (d)(3)(ii) of this section.

(i) (Reserved)

(ii) The allowable levels for volatile organic chemicals (VOC's) are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Benzene (71-43-2)	0.005
Carbon tetrachloride (56-23-5)	0.005
1,2-Dichloroethane (107-06-2)	0.005
1,1-Dichloroethylene (75-35-4)	0.007
1,1,1-Trichloroethane (71-55-6)	0.20
Trichloroethylene (79-01-6)	0.005
Vinyl chloride (75-01-4)	0.002

(iii)—(v) (Reserved)

(vi) Analyses conducted to determine compliance with paragraph (d)(3)(ii) of this section shall be conducted in accordance with a relevant method contained in "Methods for the Determination of Organic Compounds in Drinking Water," Office of Research and Development, Environmental Monitoring Systems Laboratory, EPA/600/4-88/039, December 1988, and listed separately in paragraphs (d)(3)(vi)(A) through (d)(3)(vi)(E) of this section, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Except as otherwise indicated below, copies are available from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(A) Method 502.1—"Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography" (applicable to VOC's).

(B) Method 502.2—"Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series" (applicable to VOC's).

(C) Method 503.1—"Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography" (applicable to VOC's).

(D) Method 524.1—"Measurement of Purgeable Organic Compounds in Water by Purged Column Gas Chromatography/Mass Spectrometry" (applicable to VOC's).

(E) Method 524.2—"Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry" (applicable to VOC's).

(vii) (Reserved)

* * * * *

Dated: April 23, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

Editorial Note: This document was received in the Office of the Federal Register December 28, 1992.

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58 FR 378-01, 1993 WL 674 (F.R.)
END OF DOCUMENT

APPENDIX F

NOTICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[98N-0867]

ENVIRONMENTAL PROTECTION AGENCY

[OPP-300624; FRL-5773-8]

Legal and Policy Interpretation of the Jurisdiction Under the Federal Food, Drug, and Cosmetic Act of the Food and Drug Administration and the Environmental Protection Agency Over the Use of Certain Antimicrobial Substances

Friday, October 9, 1998

*54532 AGENCIES: Environmental Protection Agency (EPA) and Food and Drug Administration (FDA).

ACTION: Notice of policy interpretation.

SUMMARY: The Food Quality Protection Act of 1996 became law on August 3, 1996. FQPA amended both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Federal Food, Drug, and Cosmetic Act (FFDCA). Among other things, FQPA changed the regulatory authority of both EPA and FDA with respect to the FFDCA's regulation of pesticide residues in or on food. This notice: (1) Sets forth legal and policy interpretations of the FFDCA as they relate to the jurisdiction of EPA and FDA over antimicrobial substances used in or on food, including food-contact articles; (2) discusses interpretations of certain terms in FIFRA and the implementing regulations relevant to the authority of the two agencies; (3) provides a description of how EPA and FDA propose to clarify the post-FQPA regulatory authority over certain antimicrobial substances; and (4) discusses how EPA and FDA plan to handle the review of petitions for antimicrobial substances that will remain under EPA's jurisdiction and for those that EPA proposes to return to FDA's regulatory authority through EPA rulemaking.

DATES: The policy set out in this notice is effective immediately. Both FDA and EPA will accept comments on this notice for 90 days from October 9, 1998.

ADDRESSES: Comments should be sent to both FDA and EPA dockets at the addresses listed below. Submit written comments identified by the appropriate docket number (for FDA 98N-0867 and for EPA OPP-300624) to:

FDA at: Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

EPA at: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to EPA: opp-docket @epamail.epa.gov. Follow the instructions under Unit VII. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. The public docket is available for public inspection in Rm. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Regarding EPA issues: William L. Jordan, Antimicrobials Division (7510W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (703) 308-6411.

Regarding FDA issues: Mark A. Hepp, Office of Pre-Market Approval Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St., SW., Washington, DC 20204-0002, Telephone: (202) 418-3098.

SUPPLEMENTARY INFORMATION:

Electronic Availability:

Internet

Electronic copies of this document and PR Notice 97P-1 are available from the EPA home page at the Federal Register-Environmental Documents entry for this document under "Laws and Regulations" (http://www.epa.gov/fedrgstr/).

Fax on Demand

Using a faxphone call 202-401-0527 and select item 6108 for a copy of the PR Notice and select item 6113 for a copy of this Federal Register notice.

EPA and FDA are issuing this joint notice to clarify, subsequent to the enactment of the Food Quality Protection Act of 1996 (FQPA), the jurisdiction over antimicrobials that are used in or on food, including those used in or on edible food, and those used in the manufacture of, or in or on, food-contact articles. In addition, the agencies are setting forth a proposed allocation of jurisdiction for these antimicrobials. Implementation of some of these decisions would require EPA rulemaking. Such rulemaking, if finalized as proposed, would reestablish FDA's regulatory authority over certain antimicrobial substances. Therefore, the agencies are presenting an interim plan to coordinate the review of petitions for the antimicrobial substances that would be affected by any proposed EPA rulemaking.

This joint notice is subject to FDA's good guidance practices (GGPs) Level 1 guidance (62 FR 8961, February 27, 1997). FDA will not solicit public input prior to implementation because the guidance presents a less burdensome policy that is consistent with the public health. This guidance does not create or confer any rights for or on any person and does not operate to bind FDA, EPA, or the public.

I. Legal Background

As described more fully below, EPA regulates the sale, distribution, and use of "pesticides" under FIFRA, 7 U.S.C. 136 et seq. Historically, EPA and FDA have shared regulatory authority under the Federal Food, Drug, and Cosmetic Act (FFDCA),

21 U.S.C. 321 et seq. over the residues of such "pesticides" in or on food. The FQPA of 1996 amended FFDCA in ways that alter EPA's and FDA's jurisdiction over certain pesticides with antimicrobial uses.

A. EPA Jurisdiction and Authorities Under FIFRA

In general, FIFRA gives EPA authority to regulate the sale, distribution, and use of a "pesticide." A "pesticide" is defined as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, . . ." (FIFRA section 2(u)). The term "pest" includes "(1) any insect, rodent, nematode, fungus, weed, or (2) any . . . virus, bacteria, or other microorganism which the Administrator declares to be a pest" (FIFRA section 2(t)). As a result of these broad definitions, EPA regulates, as FIFRA pesticides, a wide variety of chemical substances marketed for a diverse array of uses. For example, EPA regulates, as pesticides, substances used to control weeds and fungi on crops, and microorganisms that may be present on permanent or semi-permanent surfaces, such as counter tops and food processing equipment that may come in contact with food.*54533

It should be noted that FIFRA defines "fungus" as "any non-chlorophyll-bearing thallophyte . . . as for example . . . mildew, mold, yeast, and bacteria . . .," but the definition specifically excludes those organisms when "on or in processed food, beverages, or pharmaceuticals" (FIFRA section 2(k)). Further, EPA has broadened this statutory exclusion in its FIFRA regulations at 40 CFR 152.5(d). Specifically, under this rule, an organism is not considered a "pest" if it is a "fungus, bacterium, virus, or other microorganisms [sic] . . . on or in processed food or processed animal feed, beverages, drugs, . . . or cosmetics . . . ." In applying this exclusion, EPA has historically interpreted the words "processed food" and "processed animal feed" as they are commonly understood--food that has undergone processing and is intended to be consumed immediately or after some further processing or preparation. Because the commonly understood meaning of these terms applies to edible food articles, EPA has not considered food-contact items (such as paperboard and ceramic ware) to be "processed food" within the meaning of that term in FIFRA and EPA's implementing regulations. Thus, EPA has regarded any antimicrobial substance used in or on paper, paperboard, or other food-contact items as a "pesticide" under FIFRA.

> FNThe discussion in the paragraph above, however, does not purport to interpret the FFDCA definition, but rather to address the meaning of the terms "processed food" and "processed animal feed" used in FIFRA and EPA's implementing regulations.

With minor exceptions, no pesticide product may be sold or distributed unless EPA has licensed or "registered" the product (FIFRA section 12(a)(1)(A)). EPA registers products on the basis of data showing that the pesticide, when used in accordance with the terms and conditions of registration and in accordance with widespread and commonly recognized practice, will perform its intended function without causing "unreasonable adverse effects on the environment" (FIFRA section 3(c)(5)). Through registration, EPA regulates the composition, packaging, and labeling of pesticides. The labeling of a pesticide product includes information prescribing how a product may be used and generally contains directions specifying the sites on which the product may be used, the amount that may be applied, the frequency of application, and appropriate precautions necessary to reduce risks. It is unlawful to use a registered pesticide in a manner inconsistent with its labeling (FIFRA section 12(a)(2)(G)).

B. EPA and FDA Jurisdiction and Authorities Under FFDCA Prior to FQPA

The FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that is "adulterated" (FFDCA section 301(a)). Food is deemed adulterated, among other reasons, "if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a); or if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409" (FFDCA section 402(a)(2)(B), (C) (emphasis added)). As discussed more fully below, prior to the enactment of FQPA, some FIFRA "pesticides"--primarily agricultural chemicals--were "pesticide chemicals" under FFDCA; other FIFRA "pesticides"-- including antimicrobials--were "food additives" under FFDCA. Thus, pre-FQPA, both EPA and FDA had responsibilities under FFDCA for the regulation of residues in food resulting from use of substances considered "pesticides" under FIFRA. Each agency's pre-FQPA authority is described directly

below. Section C in this unit explains the changes in each agency's authority brought about by FQPA.

1. EPA jurisdiction and authorities. Under Reorganization Plan 3 of 1970, which created the Environmental Protection Agency, EPA assumed the authority in FFDCA to set tolerances, and exemptions from the requirement of a tolerance, for "pesticide chemicals" (5 U.S.C. App. I, 84 Stat. 2086). At that time, the FFDCA defined a "pesticide chemical," as "any substance which . . . is a 'pesticide' within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136(u)) as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities" (FFDCA section 201(q), 21 U.S.C. 321(q) (1994) (amended 1996)). Thus, in addition to registering pesticides under FIFRA, EPA regulated the presence of the residues in food of FIFRA "pesticides" resulting from their use in or on raw agricultural commodities.

It is important to note that the definition of "pesticide chemical" in FFDCA was narrower than FIFRA's definition of "pesticide," and therefore EPA had jurisdiction over residues in or on food for only some FIFRA pesticides. As a practical matter, EPA's authority under FFDCA extended only to pesticides used in agricultural production--e.g., weed killers, fungicides, growth regulators, and insecticides applied to growing crops and stored raw agricultural commodities.

In general, a "pesticide chemical" in or on a raw agricultural commodity was considered "unsafe" unless there was a tolerance or an exemption from the requirement of a tolerance for the pesticide chemical and the residue of the pesticide chemical conformed to the terms of the tolerance or exemption. See FFDCA section 408(a)(1), 21 U.S.C. 346a(a)(1) (1994) (amended 1996). A tolerance sets out the maximum amount of a residue that may legally remain on a particular food. For example, EPA established a tolerance of 0.05 parts per million (ppm) of the weed killer alachlor in peanuts. See 40 CFR 180.249. Any residue of alachlor over that amount would cause the peanuts to be adulterated. An exemption from the requirement of a tolerance represents a determination by EPA that any amount of residue of a specific pesticide chemical expected to be present in or on a raw agricultural commodity as a result of its use would be safe. For pesticides subject to a tolerance exemption, there is no numerical limit on the amount of permitted residue.

In its administration of FIFRA and FFDCA, EPA has adopted policies to ensure the coordinated application of both statutes. Specifically, EPA will not register a pesticide under FIFRA if its use is expected to result in residues in food unless such use complies fully with the FFDCA. See 40 CFR 152.112(g) and 152.113(a)(3).

2. FDA jurisdiction and authorities. FDA was (and remains) responsible for the regulation of "food additives" that are not "pesticide chemicals." Prior to the FQPA, the definition of "food additive" included residues in food of certain FIFRA "pesticides" that were not FFDCA "pesticide chemicals." The term "food additive" was defined as: "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized as safe . . . " (FFDCA section 201(s) (1990) (amended 1996)). The definition of "food additive" specifically excluded a "pesticide chemical in or on a raw agricultural commodity" (FFDCA section 201(s)(1)(1990) (amended 1996)). Under this definition, the term "food additive" did not include pesticide chemicals in or on a raw agricultural commodity but did include pesticide chemicals in foods that were not raw agricultural commodities. EPA *54534 was responsible for the establishment of tolerances or food additive regulations under section 409 for pesticide chemical residues in food. FDA was responsible for the establishment of "food additive regulations" for all food additives except those that were also pesticide chemicals. FDA did set food additive regulations for food additives that were FIFRA pesticides, but not FFDCA pesticide chemicals.

As a practical matter, FIFRA pesticides that were regulated by FDA as food additives prior to FQPA were for antimicrobial uses. These FDA-regulated substances included products used as sanitizers and disinfectants for permanent or semi-permanent food-contact surfaces; as materials preservatives in products like adhesives, coatings, and latex solutions that could be used to manufacture food packaging materials or which could otherwise come into contact with food; and as slimicides added during the process of making paper and paperboard used to package food. In sum, for each of these categories, EPA registered antimicrobial substances as a pesticide under FIFRA for the food uses, only after FDA had made a determination that the use of the products were safe under section 409 of FFDCA.

Finally, FDA was (and remains) responsible for enforcement of all FFDCA pesticide tolerances and of food additive regulations. FDA can request seizure of a food or other enforcement action when a pesticide residue on food does not conform to an established tolerance or food additive regulation, or when there is no tolerance, exemption from the requirement of a tolerance, or food additive regulation in place.

C. Changes in EPA and FDA Authority Under FFDCA Resulting From FQPA

While FQPA made a number of changes to both FIFRA and FFDCA, this notice focuses only on changes that alter the regulatory responsibilities of EPA and FDA for establishing FFDCA section 408 tolerances, exemptions from the requirement for a tolerance, and food additive regulations with respect to antimicrobials. Specifically, this section discusses: FQPA definitions of "pesticide chemical," "pesticide chemical residue," and "food additive"; the authority in FFDCA section 201(q)(3) to except substances from the definition of "pesticide chemical"; the transition provisions in FFDCA section 408(j); and the new statutory standard in FFDCA section 408 for the establishment of a tolerance and an exemption from the requirement for a tolerance.

1. Definitions of "pesticide chemical," "pesticide chemical residue," and "food additive." FQPA redefined "pesticide chemical" in FFDCA to mean: "any substance that is a pesticide within the meaning of FIFRA, including all active and inert ingredients of such pesticide" (FFDCA section 201(q)(1)). Notably, this new definition eliminates the restriction in the pre-FQPA definition of "pesticide chemical" that the pesticide be used in the production, storage, or transportation of a raw agricultural commodity.

FQPA also amended the definition of "food additive" (FFDCA section 201(s)). The FQPA amendments did not affect the primary definition of "food additive." As before, the term food additive is defined broadly and includes "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food. . . " (FFDCA section 201(s)). However, the FQPA amendments did revise the food additive definition's exclusions. Specifically, the term "food additive" now excludes "a pesticide chemical residue in or on a raw agricultural commodity or processed food" (FFDCA section 201(s)(1)). As a result of these two changes, antimicrobial pesticides formerly regulated by FDA as "food additives" under section 409 of FFDCA, are now considered "pesticide chemicals" and regulated by EPA under section 408 of FFDCA .

FQPA also added a definition of "pesticide chemical residue" (FFDCA section 201(q)(2)). This term means any residue in or on food of a pesticide chemical or any other substance that results primarily from the metabolism or degradation of a pesticide chemical. This definition makes explicit the long-standing EPA interpretation that the term "pesticide chemical" includes the chemical compounds formed through the breakdown or metabolism of pesticidally active and inert ingredients in a pesticide formulation.

2. Exception authority. FQPA added a clause to the subsection defining "pesticide chemical" and "pesticide chemical residue" that gives EPA the authority, in certain circumstances, to "except" or exclude otherwise covered substances from these definitions (FFDCA section 201(q)(3)). Specifically, EPA may exclude a substance from the definition of a "pesticide chemical" or a "pesticide chemical residue" if EPA makes two findings: (1) The presence of the substance in a raw agricultural commodity or processed food is due primarily to natural causes or to human activities not involving the use of the substance for a pesticidal purpose in the production, storage, processing, or transportation of a raw agricultural commodity or processed food; and (2) after consultation with the Secretary of Health and Human Services, the substance is more appropriately regulated under provisions of the FFDCA other than section 402(a)(2)(B) and 408.

3. Transition provision. FQPA added a provision to the FFDCA to assure an orderly transition to the new regulatory system. All previously issued regulations under FFDCA section 406, 408, and 409, which authorized the presence in food of any substance that is a pesticide chemical residue, remain in effect unless modified or revoked (FFDCA section 408(j)). Thus, existing food additive regulations issued by FDA for antimicrobial substances that are pesticides remain valid, and food is not

adulterated by residues of such substances that conform to the applicable food additive regulations.

4. Statutory standard for section 408 tolerances and exemptions. FQPA amended section 408 of FFDCA to establish a new standard for making decisions to establish tolerances or exemptions from the requirement of a tolerance for pesticide chemical residues. In order to establish or leave in effect either a tolerance or an exemption, EPA must conclude that the pesticide chemical residue in food would be "safe" (FFDCA section 408(b)(2)(A)(i), (c)(2)(A)(i)). "Safe" is further defined to mean "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information" (FFDCA section 408(b)(2)(A)(ii), (c)(2)(A)(ii)). The amendments also direct EPA to consider a variety of factors in making decisions under the new standard. These factors include: the potential for greater sensitivity or exposure for infants and children to the pesticide chemical residue; and the cumulative effects of the pesticide chemical residue and other substances that have a common mechanism of toxicity. See FFDCA section 408(b)(2)(C) and (D).

5. Summary. The FQPA amendments have expanded the definition of "pesticide chemical" in FFDCA to correspond in scope to the definition of "pesticide" in FIFRA. As a result, so long as a substance is a "pesticide" under FIFRA, EPA now has jurisdiction to regulate the substance under both FIFRA and FFDCA. EPA also has the authority to "except" substances from *54535 the definitions of "pesticide chemical" or "pesticide chemical residue." Such an exception would transfer the regulatory responsibility for such substances to FDA, without yielding regulatory authority under FIFRA over the use of the pesticide. Notwithstanding these changes, all previously issued approvals that allow residues of pesticides in food remain valid under the transition provisions. All pesticides that are EPA's regulatory responsibility under FFDCA are subject to the new safety standard of FFDCA section 408.

II. Background

In addition to considering the changes to the legal framework resulting from FQPA, EPA and FDA evaluated whether the jurisdictional change brought about by FQPA for certain antimicrobial substances resulted in the most efficient regulatory outcome. The agencies took several factors into account in the deliberations and tentatively concluded that an alternative jurisdictional approach for certain antimicrobial substances would be more appropriate. Principally, the two agencies have concluded that the jurisdiction under FFDCA for antimicrobial substances should be allocated in a way that promotes protection of public health, and uses limited public resources efficiently. The factors that the agencies considered are discussed more fully in sections A and B of this unit.

A. Promotion of Public Health

In recent years, the scientific community has identified the contamination of food by pathogenic microbes as both a serious and growing problem affecting the overall safety of the food supply. The Federal government, working through multiple agencies such as FDA, EPA, and the Department of Agriculture, Food Safety and Inspection Service, is using its resources and regulatory authorities to address this problem in a concerted fashion. Some of the more significant initiatives are FDA's Hazard Analysis and Critical Control Point (HACCP) program for the seafood industry, USDA's HACCP program for the meat and poultry industry, and the possible expansion by FDA of HACCP to other segments of the food industry. HACCP starts with the preparation of a hazard analysis for each food processing facility and then a plan designed to prevent hazards from occurring in the production of food through a range of available control techniques and to respond to deviations from the prevention plan.

FDA is especially concerned with a growing problem of pathogens in fruits, vegetables, and unpasteurized juices. FDA's concern extends to both domestic and imported foods. This includes contamination of foods with Escherichia coli 0157:H7, which caused a serious human illness outbreak involving unpasteurized apple juice in the fall of 1996, problems associated with Listeria monocytogenes in cut vegetables, and others. As noted, FDA considers HACCP to be a state of the art approach to dealing with these problems. For HACCP to be effective, however, regulatory agencies must be sure that industry HACCP plans include controls that will ensure that the public is adequately protected from pathogens in foods. In order to accomplish

this, FDA expects that it will, over time, establish a number of performance standards to assure the effective control of pathogens in foods.

FDA and EPA must ensure a coordinated approach if these concerns with microbial contamination are to be effectively addressed. For example, one technique for reducing microbial contamination of foods is the appropriate use of antimicrobial chemicals. Therefore, in evaluating jurisdictional alternatives, the two agencies have tentatively decided to recognize and give considerable weight to the benefits that would result from FDA having broad regulatory authority over the use of antimicrobial chemicals in food processing facilities. This coordinated approach will allow FDA to move forward in proposing, for instance, that juices sold for human consumption be subject to a process that reduces, controls, or eliminates pathogens, and therefore, will be equivalent to pasteurization in its effect. An equivalent process may include the use of antimicrobials. Antimicrobials must not only kill pathogens; assurance is needed that after antimicrobials are applied, the food meets the performance standard that FDA has determined is necessary to protect the public health. Furthermore, the food must meet the performance standard in a real world production environment.

The use of antimicrobials in food production may be a complex undertaking. For example, the use of an antimicrobial that might not be capable of meeting the performance standard by itself at one processing step can be combined with other pathogen reduction efforts at other processing steps. It is important that together, these controls achieve the desired public health objective. The total process, including the antimicrobial use, can be considered in determining whether the process is adequate to protect the public from pathogens.

FDA and EPA, after considering these situations and FDA's role and experience in dealing with pathogens in foods, have tentatively concluded that FDA should have broad regulatory authority over the use of antimicrobial substances in food processing facilities. Presently, FDA has regulatory authority over such substances when used in or on processed edible foods. However, the intended use of antimicrobial substances on certain food-contact articles and on raw agricultural commodities is within EPA's regulatory purview. Therefore, the proposed allocation of jurisdiction, described in Unit III. of this notice, would expand FDA's regulatory authority to include antimicrobial substances used on certain food-contact articles and on raw agricultural commodities in food processing facilities.

B. Efficient Use of Public Resources

Congress' amendment to the definition of "pesticide chemical residue" in FFDCA, which now includes such residues on processed food in addition to those residues on raw agricultural commodities, may be viewed as streamlining the regulatory system by consolidating responsibilities for regulating "pesticides" with antimicrobial activity in EPA. One consequence of FQPA is to allow EPA to coordinate the parallel decision-making process of registration under FIFRA and tolerance setting under FFDCA for antimicrobial substances that are "pesticides" under FIFRA. This is consistent with other FQPA amendments that direct EPA to streamline its registration process for non-food use antimicrobial pesticides. See FIFRA section 3(h).

The FQPA amendments did not affect the current regulatory framework in FIFRA which exempts, by statute, certain microbes in or on processed food from the definition of "pest." Nor did these amendments affect the Administrator's authority to declare by regulation that certain microbes are not "pests." Thus, antimicrobials directed against microbes that are in or on processed edible food remain subject to FDA's regulatory authority as food additives post-FQPA.

However, this new regulatory scheme created by FQPA differs significantly from the previous regulatory scheme in place for over 25 years for certain indirect food additives. Antimicrobial substances applied to or incorporated in food-contact articles but not used directly in or on edible processed food were regulated by FDA as food additives *54536 because of their potential migration to food. FDA and EPA have extensive regulatory experience with this pre-FQPA jurisdictional scheme and have developed considerable understanding and experience with the policies and procedures of the respective agencies.

To the extent that the regulated community has expressed its views, it expressed a preference for retaining, to the greatest

extent possible, the pre-FQPA regulatory scheme regarding antimicrobials in or on food-contact articles. Such an approach, it argued, could involve fewer delays because ongoing reviews would continue at FDA where such reviews have historically been performed. Moreover, by retaining the pre-FQPA scheme, products regulated by FDA would not be subject to the requirement in FFDCA section 408 to pay a fee.

Implementing the new statutory scheme, therefore, would involve adjustments for both the regulated industry and the Federal agencies. During the transition, decision-making would likely experience considerable delays. Moreover, during the transition both agencies would face additional, new work associated with any transfer of responsibilities. To the extent that the agencies use rulemaking to restore the pre-FQPA allocation of jurisdiction, these problems are reduced.

In conclusion, EPA and FDA weighed all of these considerations in formulating the approach set forth in Unit III. of this notice regarding the allocation of regulatory responsibility for antimicrobial substances used in food-contact articles and food packaging materials. The agencies reached decisions that they believe reflect the most appropriate balance of the competing considerations based upon currently available information. This proposed allocation of responsibilities is described more fully in Unit III. below.

III. Allocation of Regulatory Responsibilities Under FFDCA in Light of FQPA Amendments

A. Summary

EPA and FDA propose to divide the universe of antimicrobial substances regulated under the FFDCA, and potentially affected by the FQPA amendments, into the following categories. Some of these categories are the consequence of statutory provisions; others would be established through rulemaking. Sections B. through F. of this unit discuss each of the following categories in detail. Section G. of this unit provides a table summarizing the categories.

1. Antimicrobial substances directed against microbes in or on edible food, animal drinking water, and process water that contacts edible food (see section B. of this unit).

a. EPA: antimicrobials used in or on raw agricultural commodities, or in process water contacting such commodities, in the field, or in a facility where only one or more of the following activities occurs: washing, waxing, fumigating, and packing of raw agricultural commodities, or during transportation of such commodities between the field and such facility; antimicrobials used in or on raw agricultural commodities for consumer use; antimicrobials that are not drugs used in animal drinking water.

b. FDA: antimicrobials used in or on processed food or processed animal feed; antimicrobials used in or on raw agricultural commodities or in process water contacting such commodities (other than those described in section III.A.1.a. of this unit), in a facility where such commodities are prepared, packed, or held (hereinafter "food processing facility" (refer to section B. of this unit for a description of such facilities));

2. Antimicrobial substances directed against microbes on permanent or semi-permanent food-contact surfaces (see section C. of this unit). [Note: impregnated antimicrobials are addresssed in paragraphs 4. and 5. below.]

a. EPA: sole jurisdiction.

b. FDA: no jurisdiction.

3. Antimicrobial substances used in the production of food packaging materials and in or on such finished materials including plastic, paper, and paperboard (see section D. of this unit).

a. EPA: no jurisdiction.

b. FDA: sole jurisdiction.

4. Antimicrobial substances used in production of food-contact articles, other than food packaging, for which there is no ongoing intended antimicrobial effect in the finished article (see section E. of this unit).

a. EPA: no jurisdiction.

b. FDA: sole jurisdiction.

5. Antimicrobial substances incorporated into food-contact articles, other than food packaging, that have an intended antimicrobial effect on the finished article itself, including the article's surface (see section F. of this unit).

a. EPA: jurisdiction over active pesticidal ingredients.

b. FDA: jurisdiction over inert ingredients in such pesticides.

B. Antimicrobial Substances Directed Against Microbes in or on Edible Food, Animal Drinking Water, and Process Water that Contacts Edible Food

The FQPA amendments did not change FDA's and EPA's jurisdiction over antimicrobials used to control microbes on raw agricultural commodities and processed food (within the meaning of the term "processed food" in 40 CFR 152.5). Antimicrobial substances directed against microbes in water in which raw agricultural commodities are washed, or directed against microbes in or on raw agricultural commodities, whether the antimicrobials are added to the commodities directly, or indirectly through the addition of the antimicrobial to water in which the commodities are washed, are subject to EPA's regulatory authority as "pesticides" under FIFRA and "pesticide chemicals" under FFDCA. This category includes antimicrobial substances used in the washing of fresh fruits and vegetables. EPA also regulates antimicrobial substances added to drinking water of cattle, poultry, and other food animals.

Antimicrobial substances directed against microbes in or on processed food are not subject to EPA's regulatory authority either under FIFRA or FFDCA. This is a result of a jurisdictional division that existed both before and after the FQPA amendments. The definition of "pest" in EPA's implementing regulation at 40 CFR 152.5(d) specifically excludes "microorganisms . . . on or in processed food . . . ." See Unit II.A. of this notice. Therefore, antimicrobial substances directed against microorganisms on or in processed food are not "pesticides" under FIFRA. Since these substances are not pesticides under FIFRA, they are not "pesticide chemicals" under FFDCA. This category includes substances such as those listed in 21 CFR 172.165, 173.315, and 173.320. EPA has had, and will have, no role in the regulation of substances for these uses; they do not require registration under FIFRA nor tolerances under FFDCA section 408.

Many existing and proposed applications involve the addition, inside a food processing facility, of antimicrobial substances to process water that contacts fruits, vegtables, or other foods. According to the Memorandum of Understanding (MOU) between FDA and EPA on the jurisdiction over substances in drinking water (44 FR 42775, July 20, 1979), FDA has responsibility under FFDCA section 409 for water, and substances in water (including antimicrobials) used in food *54537 and for food processing. (44 FR 42775, July 20, 1979). Under this MOU, EPA has, in the past, refrained from regulating such antimicrobial substances under FIFRA, FFDCA, the Safe Drinking Water Act, 42 U.S.C. 300f et seq., and the Toxic Substances Control Act, 15 U.S.C. 2601 et seq. More recently, however, EPA has exercised its authority over antimicrobials added to process water inside a food processing facility, if that water contacts a raw agricultural commodity, whether or not such raw agricultural commodity is later subjected to processing.

FNUnder the MOU, EPA has regulatory responsibility for substances added to a public drinking water system before the water enters a food processing establishment.

FQPA did not alter the regulatory framework in FIFRA that determines whether antimicrobial substances used in or on raw agricultural commodities or processed food are classified as FIFRA "pesticides." Despite this fact, a more efficient allocation of jurisdiction over antimicrobials that are used in or on both raw agricultural commodities and processed food appears warranted, given FDA's interest in regulatory authority over such substances in food processing facilities.

As discussed above, under the current regulatory scheme, whether EPA or FDA has jurisdiction over an antimicrobial used on edible food depends on whether the antimicrobial substance is applied to a raw agricultural commodity or processed food. Yet it is sometimes difficult to determine whether certain activities constitute "processing" or are merely post-harvest treatment activities. EPA made such a distinction for dried commodities (61 FR 2386, January 25, 1996) and found that, in the legislative history of FFDCA section 408, there was ambiguity in whether certain types of drying were considered "processing." Moreover, raw agricultural commodities that are treated with antimicrobials inside a food processing establishment or facility may be culled, with some of these commodities undergoing further processing and others leaving the facility without any further processing. This practice makes it difficult to determine which specific commodities will remain "raw agricultural commodities" and which will be processed.

The agencies believe that it makes little sense to have the same antimicrobial substance require both a section 408 tolerance and a section 409 food additive regulation when the food, whether raw or processed, is undergoing the same activity, e.g., washing. Therefore, EPA intends to propose an amendment to 40 CFR 152.5 to exclude from the definition of "pest" microbes that are in or on raw agricultural commodities or in process water used on such commodities in a food processing facility. Thus, antimicrobials that are both used inside a food processing facility and applied either directly to edible food, whether raw agricultural commodities or processed food, or to process water that contacts such edible food would not be FIFRA "pesticides" nor FFDCA "pesticide chemicals," but instead would be subject to regulation as FFDCA "food additives" under FFDCA section 409.

1. Facilities. The proposed change in the allocation of jurisdiction over antimicrobials used in or on raw agricultural commodities, described in section III.A.1.b. of this unit, is limited to those commodities in "food processing facilities." The term "food processing facility" would include those locations where food is prepared, packed, or held, except for in the field where raw agricultural commodities are subject to certain post-harvest treatments. Thus, the term includes slaughtering or manufacturing facilities for meat, poultry, seafood, and produce; retail facilities such as restaurants, grocery stores, institutions, and food vending operations; and mobile food facilities such as trains, planes, and vessels. FDA's jurisdiction over antimicrobials that are used on "processed" food in such locations remains unchanged by FQPA; such antimicrobials remain subject to regulation as food additives under section 409 of FFDCA.

EPA and FDA realize that certain food processing facilities are part of a farming operation where antimicrobial use on raw agricultural commodities would not constitute uses described in section III.A.1.a. of this unit. For example, egg sanitizing may occur "on the farm" as part of an operation with the same types of food handling activities as those that occur in other food processing facilities. Antimicrobials used in such an operation would be subject to food additive approval by FDA.

2. Ethylene and propylene oxides. As a result of the agreement between FDA and EPA, the allocation of regulatory jurisdiction under FFDCA over antimicrobial substances used on edible food would, for the most part, correspond to the allocation that existed prior to enactment of FQPA. As discussed, the major change would affect antimicrobial substances used on raw agricultural commodities inside food processing facilities. There is, however, an additional set of antimicrobial uses--ethylene oxide and propylene oxide use on whole and ground spices--for which the proposed allocation would represent a difference from the current regulatory scheme. All uses of ethylene oxide on spices have been regulated by EPA under FFDCA section 408. Since these uses of ethylene oxide take place inside food processing facilities, the proposed allocation would give FDA exclusive jurisdiction over these uses under FFDCA section 409. This situation is further complicated by the fact that these active ingredients also have insecticidal properties that could only be regulated by EPA under both FIFRA and FFDCA. EPA and FDA are considering, in light of the long history of regulation of this chemical and these specific uses

by EPA under FFDCA section 408, whether to address the uses differently from the general approach described above. At a minimum, EPA's proposed rule will seek public comment on the implications for different regulatory schemes for these uses under FFDCA.

In summary, FDA and EPA agree that because it is difficult to ascertain whether certain food will remain a raw agricultural commodity or become a processed food when entering food processing facilities, it would be more efficient to allocate regulatory responsibility for antimicrobials that are used on raw agricultural commodities in such facilities to FDA. Moreover, it would be consistent with the promotion of public health and FDA's interest in the application of HACCP principles to food production. Thus, antimicrobials that are used inside a food processing facility, including those used in process water contacting edible food, regardless of whether the food is "processed," would not be FIFRA "pesticides" nor FFDCA "pesticide chemicals," but instead would be "food additives" under FFDCA section 409.

Antimicrobials that are directed against microbes in or on raw agricultural commodities, as described in section III.A.1.a. of this unit, would remain FIFRA "pesticides" and FFDCA "pesticide chemicals" and thus require pesticide registration under FIFRA and a tolerance or exemption from the requirement of a tolerance under FFDCA. Antimicrobials that are used by the consumer in or on raw agricultural commodities in the household would remain FIFRA "pesticides" and thus would also require FIFRA registration. Moreover, such antimicrobials would be FFDCA "pesticide chemicals," but would not require a tolerance or an exemption from the requirement of a tolerance where such food is not "held for sale" within the meaning of FFDCA. Nonetheless, EPA will continue to *54538 conduct the same safety evaluation of dietary exposure to antimicrobials used in consumer households as it does for tolerances issued under FFDCA section 408.

3. Labeling of products used in retail facilities. Historically, FDA has had limited involvement in the regulation and enforcement activities affecting retail establishments, including restaurants and grocery stores. FDA has directed its efforts toward providing technical assistance to state and local governmental agencies that, as a practical matter, have primary responsibility for regulating the retail segment of the food industry. Providing a model food code has been the central mechanism through which FDA, as a lead Federal food control agency, has promoted uniform implementation of national food regulatory policy among the several thousand Federal, state, tribal, and local agencies that carry out the primary oversight of this industry component.

Although the food code provides referenced information about the approved use of antimicrobials in or on food, EPA and FDA believe that directions for use should be included on the labeling of such substances. The labeling would ensure that a person using such a product in the retail setting will have adequate directions for use readily available. Therefore, as part of its exercise of regulatory authority over the use of those antimicrobial substances, FDA is planning to propose to require that a manufacturer provide adequate directions for use to ensure compliance with the applicable food additive regulation. These directions would include the conditions of safe use required under FFDCA section 409(c)(1). The conditions of safe use require adequate directions to achieve the intended technical effect.

Consistent with its authority under FFDCA section 409(c)(3)(B), FDA believes that a product that is intended to achieve an antimicrobial effect may require a label with adequate directions to achieve such effect so that the use of the product would not promote deception of the consumer. Specifically, section 409(c)(3)(B) prohibits FDA from approving a food additive if the proposed use would result in the misbranding of food within the meaning of FFDCA section 403(a)(1). Under section 403(a)(1) of FFDCA, a food is misbranded if its labeling is false or misleading in any particular.

Section 201(n) of the FFDCA provides context to what is meant by "misleading" in FFDCA section 403(a)(1). Under FFDCA section 201(n), when determining whether a product is misbranded, FDA is to take into account not only the representations made about the product, but also the extent to which the labeling fails to reveal facts material in light of such representations made or suggested in the labeling or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual. See 21 CFR 1.21. FDA believes that directions to achieve an antimicrobial's intended technical effect may be a material fact with respect to the consequences which may result from the use of the antimicrobial. For example, an antimicrobial that is intended to kill pathogenic microbes and fails to provide directions to achieve such effect may result in

adverse consequences to the consumer from ultimate consumption if the antimicrobial is not used appropriately. Therefore, if such labeling is required for the antimicrobial's approval for use as a food additive, the absence of such labeling would constitute misbranding under FFDCA section 403(a)(1). In general, FDA believes that the concept of "material fact" is one that should be applied on a case-by-case basis.

C. Antimicrobial Substances Used to Sanitize or Disinfect Permanent or Semi-Permanent Food-Contact Surfaces

Products intended for the uses in this category have the same regulatory status under FIFRA, both before and after FQPA. Because they are directed against pests, i.e., against microbes that are not excluded by FIFRA or implementing regulations from the definition of "pest," antimicrobial substances used to sanitize or disinfect environmental surfaces are "pesticides" under FIFRA. This category includes antimicrobial substances that are used in or on equipment in food production facilities such as farm bulk tanks and milking machines; in manufacturing facilities such as meat saws/grinders, shellfish skimmers, and in-plant product conveyance systems; in retail food facilities such as slicers, cutting surfaces, dishwashing machines, and kitchen utensils and tableware; and in mobile facilities such as bulk tankers used for liquid eggs or dairy products. Such products must be registered by EPA under FIFRA prior to marketing.

The use of these products is also widely specified and referenced in FDA's model codes pertaining to the milk, retail food, and shellfish industries. These products are considered to be "public health pesticides" under FQPA and, therefore, EPA will coordinate with FDA as part of the PHS in determining the safe and necessary use of these products.

As explained in Unit I.A. of this notice, EPA does not regard food-contact surfaces as "processed food" within the meaning of FIFRA section 2(k) and the regulations at 40 CFR 152.5(d). EPA and FDA have tentatively agreed to treat substances used to disinfect reusable food packaging materials, e.g. beverage containers, differently from antimicrobial pesticides used to disinfect or sanitize environmental surfaces (refer to discussion in section D. of this unit).

Before the FQPA amendments, products used to sanitize or disinfect permanent or semi-permanent food-contact surfaces were not considered "pesticide chemicals" under FFDCA because they were not used in the production, storage, or transportation of raw agricultural commodities. Therefore, these products were regulated as "food additives" by FDA under FFDCA section 409. Food additive regulations for this category of products appear in 21 CFR 178.1010.

Under FQPA, products in this category are "pesticide chemicals"because they are FIFRA pesticides, and thus, no longer within the scope of the term "food additive." Consequently, they are regulated under FFDCA section 408 by EPA. Because of the transition provisions in FQPA, previously issued food additive regulations remain in effect for substances in this category.

FDA and EPA have agreed to propose that EPA should retain jurisdiction over these products, rather than promulgate rules that would restore the pre-FQPA regulatory scheme. Many of the products in this category have non-food uses at other sites, especially sites involving potential exposure to children or other potentially sensitive groups in the general population. As a policy matter, EPA has decided it will conduct a more extensive risk assessment of such non-food uses to take into account the aggregate exposure of sensitive population subgroups. See EPA PR Notice 97-1 and FFDCA section 408(b). As part of its assessment of aggregate exposure, EPA would also evaluate the potential dietary exposure to the antimicrobial substance. Because EPA will be routinely evaluating the non-food uses of these products, the two agencies believe it would be more efficient for EPA to regulate the food uses of these products along with the non-food uses.*54539

D. Antimicrobial Substances Used in the Production of Food Packaging Materials and in or on Such Finished Materials

Under FIFRA, antimicrobial substances used in the production of food packaging materials, or used in or on such materials, are considered "pesticides." This category of products includes slimicides used in the manufacture of food-contact paper and paperboard, and preservatives added to aqueous suspensions for adhesives or coatings. Also included are antimicrobials incorporated into polymers or finished paper and paperboard coatings to kill microbes in the final food packaging or in the food

that contacts such packaging and sanitizers applied to food containers such as aseptic packaging. As discussed in Unit I.A. of this notice, none of these food packaging materials is considered a "processed food" under FIFRA regulations.

The FQPA amendments altered the regulatory authority over some of these products under FFDCA. Prior to FQPA, these antimicrobial substances were regulated under FFDCA section 201(s) as food additives, GRAS substances, or prior sanctioned substances. Even though many of these substances were FIFRA "pesticides," they were not used in the production, storage, or transportation of raw agricultural commodities. Consequently, FDA exercised authority over these chemicals in food under FFDCA. FDA food additive regulations for some of these chemicals appear in, for example, 21 CFR 175.105, 176.170, 176.300, and 178.1005. After FQPA, many of these products in this category are considered "pesticide chemicals" under FFDCA, because they are "pesticides" under FIFRA. Because of the exclusion of a "pesticide chemical" from the definition of "food additive," these substances are no longer "food additives" and are not within FDA's regulatory responsibility. Thus, EPA is now responsible for the establishment of tolerances or exemptions from the requirement of a tolerance for their residues in food under FFDCA section 408.

EPA and FDA have determined that antimicrobial substances in this category should be subject to regulation as food additives. This category includes two types of products: (1) Antimicrobial substances that are impregnated into food packaging that have an ongoing intended antimicrobial effect on the food or in or on the packaging itself, and (2) antimicrobial substances used in the production of food packaging that have no ongoing intended antimicrobial effect beyond the material production process.

For the first category, EPA plans to propose that FDA have regulatory authority over those antimicrobials impregnated in food packaging that are used against microbes on raw agricultural commodities and those used against microbes in or on the packaging itself. Antimicrobials used to kill microbes on processed food are not pesticides; therefore, FDA retains authority over food packaging impregnated with an antimicrobial that is intended to kill microbes on the packaged, processed food.

The second category includes antimicrobial substances used in the production of food packaging that have no ongoing intended antimicrobial effect in the finished materials. They are "pesticides" under FIFRA and therefore "pesticide chemicals" under FFDCA, post-FQPA. EPA intends to propose a regulatory scheme that gives FDA responsibility for this latter category of products for two reasons. First, antimicrobial substances in this category that kill microbes in materials used in the production of food packaging are part of the formulation of such materials. These substances include adjuvants and other components of the food packaging materials that are regulated as food additives by FDA. Government resources would be better used if these antimicrobial substances were regulated as food additives in conjunction with the adjuvants and other packaging components in which they are used. This approach is also more efficient for the regulated community for the same reason. The regulated community has expressed a strong preference for continuation of FDA regulation of these products under FFDCA. For both categories, the control of microbes in or on food packaging, as for example in the production of aseptically packaged food, is a very important aspect of an effective food safety program, such as HACCP. The two agencies believe that FDA will be better able to protect the public health by administering these regulatory programs--HACCP and use of antimicrobial substances in or on food packaging--than if jurisdiction were divided between EPA and FDA.

EPA intends to propose to amend the definition of "pest" in 40 CFR 152.5(d) to exclude microbes in or on food packaging or in materials used in the production of such packaging. As a result of such an amendment, antimicrobial substances directed against such microbes would not be "pesticides" under FIFRA, and thus, would not be "pesticide chemicals" under FFDCA. Instead, such products would be "food additives" subject solely to FDA's regulatory authority.

E. Antimicrobial Substances Incorporated into Food-Contact Articles, Other Than Food Packaging, with No Pesticidal Effect in the Finished Article

Antimicrobial substances incorporated into food-contact articles, other than food packaging, have historically been and are still considered by EPA as "pesticides" under FIFRA. This category includes a wide variety of registered pesticide products such as: preservatives used in latex solutions, adhesives and coatings intended for use in food-contact articles, and antimicro-

bial substances used in the manufacture of conveyer belts, cutting boards, plastic tubing, and other articles that come in contact with food during its storage, transportation, processing, or preparation. These antimicrobial substances may or may not have an ongoing antimicrobial effect in the finished food-contact article. Only those that have no intended ongoing antimicrobial effect in the finished article are discussed in this unit. Those with an ongoing pesticidal effect are considered in section F. of this unit.

Similar to products described in section D. of this unit, the regulatory status under FFDCA of antimicrobial substances incorporated into food-contact articles, other than food packaging, with no intended ongoing antimicrobial effect in the finished articles was changed by FQPA. Prior to FQPA, these products were regulated as "food additives" by FDA. Food additive regulations for these products appear in 21 CFR 175.300 and 177.2600, for example. After FQPA, these products are "pesticide chemicals" under FFDCA, and thus, within the regulatory authority of EPA.

Again, just as for antimicrobials used on or in food packaging materials, EPA and FDA have agreed that the regulatory responsibility for these antimicrobial substances should be similar to that existing before the FQPA amendments. EPA will propose to amend the definition of "pest" in 40 CFR 152.5(d) to exclude microbes in materials used in the production of food-contact articles, other than food packaging (which was previously discussed in section D. of this unit). The result of such a rulemaking would be that products for uses in this category would no longer be "pesticides" under FIFRA and would be subject to regulation as "food additives" under FFDCA section 409, instead of as "pesticide chemicals" under section 408 of FFDCA.*54540

The reasons for this proposed action are similar to those described above for antimicrobial substances used in or on food packaging materials with no intended ongoing antimicrobial effect in the finished packaging. Again, these substances are part of the formulations of materials used to produce food-contact articles. Regulation of these substances as food additives along with the other adjuvants and components would result in a more efficient use of government resources. Further, these antimicrobial substances have no intended ongoing antimicrobial effect in the finished food-contact article. Therefore, no claims for antimicrobial activity (i.e., pesticidal effect), which would be under the jurisdiction of EPA, are made for the finished food-contact article.

F. Antimicrobial Substances Incorporated into Permanent or Semi-Permanent Food-Contact Articles, Other Than Food Packaging, With an Ongoing Antimicrobial Effect

This category covers antimicrobial substances incorporated into permanent or semi-permanent food-contact articles such as conveyer belts, cutting boards, and plastic tubing for the purpose of having a pesticidal effect during the continuing life of the product, either on the food-contact materials themselves (self-protection) or on food that contacts the treated article. Antimicrobial substances intended to control or mitigate "pests" are "pesticides" under FIFRA. Therefore products in this category are subject to EPA regulation under FIFRA to the extent that the target microorganisms are "pests." It should be noted that, if the presence of the antimicrobial substance in the food-contact article is intended only to control microbes in or on "processed food," such a substance would not be considered a "pesticide" under FIFRA because microbes in or on processed food are not "pests."

At present, there are no products registered as pesticides by EPA that are intended to be incorporated in permanent or semi-permanent food-contact articles for a pesticidal purpose on the food that contacts such articles. Several companies, however, have been marketing unregistered products with such claims. For example, several companies make plastic cutting boards impregnated with an antimicrobial substance and have marketed these products with claims that the presence of the pesticidal substance can kill or control specific pathogenic bacteria or germs that cause food borne illnesses. Similar products could include antimicrobial countertops, housewares, conveyer belts, gloves, shelving, and sponges. Although no company has actually applied for registration of such product, several have approached EPA concerning their interest in marketing such products.

Prior to FQPA, products in this category would have been both "pesticides" and "food additives," but with the FQPA

amendments, these products are "pesticide chemicals" subject only to EPA regulation. FDA and EPA have tentatively decided to leave the allocation of responsibility largely as it exists after the FQPA amendments. Under this scheme, EPA will exercise FIFRA jurisdiction over the products, as well as FFDCA jurisdiction over the pesticide active ingredients, but FDA will regulate the inert ingredients in these products. If a company seeks to market an antimicrobial food-contact product, e.g. an antibacterial cutting board, EPA would be responsible for registration of the product under FIFRA.

The primary reason for EPA retaining responsibility for these products, as contrasted with its approach to the category described in section E. of this unit, is EPA's concern about claims made for the antimicrobial efficacy of these products. EPA believes that in determining whether to register such products, it would be critical not only to evaluate potential dietary and other risks, but also to ensure that, when public health claims are made, the products actually perform as claimed. EPA has considerable experience evaluating antimicrobial efficacy and making decisions about the labeling of pesticide products with differing levels of efficacy. Therefore from both an efficiency and public health protection perspective, EPA appears to be the more appropriate agency to exercise regulatory responsibility for these products.

EPA would also propose to establish a tolerance or an exemption from the requirement of a tolerance for the active ingredient in the product, under FFDCA. EPA would further need to determine under FFDCA that the inert ingredients were allowed to be present in food because, as explained before, EPA will not register a pesticide unless all ingredients in the product have the necessary approvals. Ordinarily, because the inert ingredients are part of a pesticide product, they would be regarded as "pesticide chemicals" and EPA would establish a tolerance or exemption from the requirement for a tolerance for such ingredients. As a practical matter, however, EPA expects that these antimicrobial products would be manufactured by adding antimicrobial active ingredient chemicals to products already in compliance with the applicable food additive regulations. Therefore, all of the inert ingredients in such products would likely already be regulated or permitted by FDA under the FFDCA. EPA and FDA have tentatively decided that EPA would "except" such products from the definition of "pesticide chemical" on a case-by-case basis, making the inert substances "food additives" and subject to section 409 of FFDCA. Such exceptions would be issued under the authority of FFDCA section 201(q)(3). See Unit I.C. of this notice.

G. Summary of Jurisdictional Changes

The following table summarizes the status of FDA and EPA jurisdiction for antimicrobial substances under FFDCA both before and after FQPA. This table also summarizes the jurisdictional allocation that EPA intends to propose through rulemaking.***54541**

Table 1.—EPA and FDA Jurisdiction Under FFDCA

Product Category	Before FQPA	After FQPA	After Planned EPA Rulemaking
1. Antimicrobial substances directed against microbes in or on edible food, antimicrobials that are not drugs used in animal drinking water, and antimicrobials used in process water that contacts edible food (Unit III.B.)	EPA & FDA	EPA & FDA	EPA--antimicrobials that are not drugs used in animal drinking water and antimicrobials in or on raw agricultural commodities or process water contacting such commodities in the field, or in a facility where only one or more of the following activities occurs: washing, waxing, fumigating, and packing of raw agricultural commodities, or during transportation of such commodities between the field and such facility; and antimicrobi-

			als used in or on raw agricultural commodities for consumer use. FDA--in or on processed food or processed animal feed; in or on raw agricultural commodities or process water contacting such commodities in a food processing facility as described in Unit III.A.1.b.
2. Antimicrobial substances directed against microbes on permanent or semi-permanent food-contact surfaces (Unit III.C.)	FDA	EPA	EPA
3. Antimicrobial substances used in the production of food packaging materials and in or on such finished materials, including plastic, paper, and paperboard (Unit III.D.)	FDA	EPA	FDA
4. Antimicrobial substances used in production of food-contact articles, other than food packaging, for which there is no ongoing intended antimicrobial effect in the finished article (Unit III.E.)	FDA	EPA	FDA
5. Antimicrobial substances incorporated into food-contact articles, other than food packaging, that have an intended antimicrobial effect on the finished article itself, including the article's surface (Unit III.F.)	FDA	EPA	EPA (active ingredients) and FDA (inert ingredients)

IV. Processed Food

This section provides guidance on a term that is important in defining the categories, and the resulting jurisdiction of FDA and EPA. Specifically it addresses what qualifies as a "processed food" under FIFRA.

Although FQPA and the agencies' subsequent policy agreement on their proposed approach to regulation of antimicrobials largely eliminated the importance of the distinction between raw and processed food for purposes of FFDCA tolerance setting, this distinction still affects the jurisdiction of EPA and FDA under both FIFRA and FFDCA over antimicrobial substances. Three of the proposed categories (Unit III.B., D., and F. of this notice) are based, in part, on whether the antimicrobial substance is directed against microbes on an article that is a "processed food" within the meaning of FIFRA. As explained below, FDA and EPA have developed guidance to help in the interpretation of this FIFRA term.

EPA has tentatively decided that the following post-harvest activities do not constitute processing, and that food subjected to these activities would not be considered processed food: washing, coloring, waxing, hydro-cooling, refrigeration, shelling of

nuts, ginning of cotton, and the removal of leaves, stems, and husks. EPA has tentatively concluded that the following activities constitute processing and that any food subjected to these activities becomes a "processed food": canning, freezing, cooking, pasteurization or homogenization, irradiation, milling, grinding, chopping, slicing, cutting, or peeling.

In determining which operations would be considered processing, EPA considered how such actions or operations are categorized, either explicitly or implicitly in FFDCA or its legislative history. For example, FFDCA defines a "raw agricultural commodity" as "any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing" (FFDCA 201(r)). This definition explicitly categorizes washing and coloring as non-processing operations and implicitly categorizes peeling as processing.

Similarly, the statute expressly lists several operations as qualifying as processing--canning, cooking, freezing, dehydration, or milling (FFDCA 201(gg)); see FFDCA section 402(a)(2)(C) (1990). From these examples EPA extracted the following guiding principle: processing operations are ones that alter the general state of the commodity, while non-processing operations, like harvesting, are designed only to isolate or separate the commodity from foreign objects or other parts of the plant. If EPA were writing on a clean slate, it perhaps would classify coloring differently. However, given the lack of intrusiveness involved in the coloring of certain commodities (e.g., oranges), EPA believes that categorizing coloring for such commodities as not processing is consistent with the guiding principle outlined above.

EPA has issued a policy statement under the FFDCA interpreting the term *54542 "raw agricultural commodity" and by inference "processed food" for foods that have been subjected to drying (61 FR 2386, January 25, 1996) (FRL-4992-4). Briefly, this policy states that a "raw agricultural commodity" becomes a "processed food" when it is dried, unless the purpose of the drying is to facilitate transportation or storage of the commodity prior to processing. As a practical matter, this policy means that some vegetables and fruits, such as grapes, become processed food when the commodity is dried. On the other hand, hay, nuts, rice, beans, corn, other grasses, legumes, and grains remain raw agricultural commodities even though they may have undergone some drying. EPA believes the distinction set forth in this prior FFDCA interpretation is reasonable and intends to follow it in implementing the term "processed food" under FIFRA.

The term "food processing facility," described in Unit III.B. of this notice, would include those facilities where food is subject to activities that constitute "processing" unless such activities fall within the exceptions for post-harvest treatments described earlier in this section. Included within the meaning of the term "food processing facility," are those facilities where meat and poultry are slaughtered or otherwise processed subject to the Federal Meat Inspection Act, 21 U.S.C. 601 et seq., and Poultry Products Inspection Act, 21 U.S.C. 451 et. seq. Also included within that term are facilities where antimicrobials are used in egg washing or processing subject to the Egg Products Inspection Act, 21 U.S.C. 1301 et seq. Finally, the term also includes fish processing operations, commercial fishing vessels, and retail food establishments.

Processing activities include most food handling activities, including those that are done to a carcass post-slaughter. Such activities include skinning, eviscerating, and quartering. Because such post-slaughter activities constitute "processing," the meat that is subject to such activities is "processed food" within the meaning of that term in 40 CFR 152.5(d). Therefore, the regulatory status of antimicrobials that are used on meat after slaughter is unchanged by FQPA and they are subject to regulation by FDA as food additives. Similarly, seafood that is harvested is "processed." Activities done post-harvest to seafood include, among other things, handling, storing, preparing, heading, eviscerating, shucking, or holding (21 CFR 123.3(k)(1)). Antimicrobials that are used in or on seafood, post-harvest, would also be subject to regulation by FDA as food additives. In summary, FDA's regulatory authority over the antimicrobial substances used on meat, poultry, and seafood is unchanged by FQPA because such uses constitute those that are on "processed food," not raw agricultural commodities.

V. Implementation of Legal and Policy Interpretations of FFDCA Jurisdiction

This unit of the notice discusses how EPA and FDA propose to implement the legal and policy interpretations. Unit V.A. discusses the rulemaking being planned by EPA to implement the jurisdictional allocations discussed in Unit III. of this notice. Unit V.B. describes how EPA will handle both new and pending petitions and Threshold of Regulation (TOR) requests

(see 21 CFR 170.39), that are for antimicrobial pesticides that the agencies have determined are now under EPA authority. (A petition or TOR request is considered "new" if it is submitted after publication of this notice.) Finally, Unit V.C. of this notice explains the regulatory status of products that are currently registered as pesticides and bear labeling directions for use against microorganisms that would no longer be "pests" under EPA's intended rulemaking.

A. Schedule for EPA Rulemaking to Implement Legal and Policy Interpretations

EPA and FDA have agreed that EPA will undertake rulemaking to redefine "pest." If these regulations are promulgated in final as they are proposed, the result would be to exclude from FIFRA regulation as "pesticides" any antimicrobial substance: (1) Used in or on raw agricultural commodities in a food processing facility and in process water contacting such commodities; (2) used in the production of food packaging materials and in or on such finished materials; and (3) used in materials that are incorporated into food-contact articles, other than food packaging, that have no continuing antimicrobial effect in the finished article. The exception for processed food and processed animal feed in 40 CFR 152.5 remains intact. The practical effect of this change would provide FDA with regulatory authority over antimicrobials used in or on "edible" food (including both processed food and raw agricultural commodities) in a food processing facility. EPA plans to include this redefinition in the proposed rules being issued under FIFRA section 3(h) and 25(a) in response to FQPA mandate to promulgate new regulations to streamline its registration of antimicrobial pesticides. The proposed rules should be issued in 1998, and a final rule redefining "pest" should be published in the first half of 1999.

B. Antimicrobial Substances Regulated Completely by EPA

As discussed above, EPA has several categories of antimicrobial substances within its regulatory authority. Pursuant to the proposed allocation of jurisdiction, EPA intends to retain regulatory authority for antimicrobials that are: (1) Directed against microbes in or on raw agricultural commodities or process water contacting such commodities as described in Unit III.A.1.a. of this notice; (2) used to sanitize or disinfect food-contact surfaces, not including food packaging (Unit III.C. of this notice); and (3) incorporated into food-contact articles, except food packaging, with continuing pesticidal activity, except where the target microorganisms are in or on processed food (Unit III.F. of this notice). EPA registers such antimicrobials under FIFRA and establishes tolerances or exemptions from the requirement of a tolerance for the antimicrobials and their ingredients. In addition, EPA has current regulatory authority over the three categories of antimicrobials described in Unit V.A. of this notice, for which it intends to initiate rulemaking to propose that FDA have regulatory authority over as food additives under FFDCA section 409. This portion of the notice focuses on how new and pending petitions will be handled by EPA, both for those antimicrobial substances over which EPA plans to retain regulatory authority and for those that EPA plans to propose to allocate regulatory authority to FDA through rulemaking.

EPA staff are available to meet with petitioners to discuss the status of pending petitions and procedures for submitting a new petition. If a petitioner or any other person considering submitting a petition is interested in meeting with EPA, the petitioner should contact the appropriate Branch Chief in EPA's Antimicrobials Division to schedule a meeting. Information about how to contact EPA appears in Unit VI. of this notice.

1. New petitions. Any petition to establish a tolerance or an exemption from the requirement of a tolerance filed after publication of this notice for products now regulated by EPA should be submitted to EPA in the format described in 40 CFR 180.7. In addition, the petition must contain an "FQPA Addendum." EPA has issued detailed guidance in PR Notice 97-1 providing direction on the format and types of information that EPA expects to be *54543 included in the petition to address the factors required by FFDCA to be considered as part of the safety standard of FFDCA section 408. Petitioners should address these factors as they relate to the specific chemical and use pattern that are the subject of their petition. Copies of PR Notice 97-1 are available from the EPA contacts listed in Unit VI. of this notice.

In addition, each petitioner must submit a draft Notice of Filing which EPA may use as the basis for preparing a Federal Register Notice announcing receipt of the petition. The petitioner must include in the draft notice or provide separately a summary of the petition and the information, data, and arguments submitted in support of the petition. Generally, the summary

should be no longer than five pages. This summary will be included in the Notice of Filing EPA is required to publish (FFDCA section 408(d)(3)). EPA Branch Chiefs have examples of such summaries which they will provide on request. Petitions for actions on antimicrobial substances that may ultimately be under FDA's jurisdiction, if the EPA rulemaking is finalized as it is intended to be proposed, will be under a Notice of Filing stating that the final action may be taken under FFDCA section 408 or section 409. The petition must also be accompanied by the tolerance fee required under FFDCA section 408(m) and 40 CFR 180.33.

Once EPA receives a complete, new petition, the Agency will issue a Notice of Receipt in the Federal Register (FFDCA section 408(d)(3)). The Notice will include the summary of petition and data, information, and arguments supporting the petition (FFDCA section 408(d)(2)(A)(i)(I)). EPA will review the petition and take final action as quickly as its resources and other, statutorily mandated, priorities allow.

2. Pending petitions. EPA is working with FDA to complete work, as expeditiously as possible, on a group of pending petitions. Prior to enactment of FQPA, FDA received but was unable to complete action on a number of petitions and TOR requests. FDA continued to work on these actions and made progress in these reviews. In addition, since FQPA became law, FDA has received additional petitions and TOR requests. FDA has taken no action with regard to any petition submitted after enactment of FQPA for an antimicrobial substance for which FDA questioned its jurisdiction as a result of FQPA.

EPA places a high priority on completing the review of these pending actions. Therefore, EPA is working with FDA to transfer the petitions and associated FDA evaluations to EPA, so that EPA can complete the review of these petitions as quickly as possible.

The transfer of the petitions and associated evaluations to EPA must conform to the restrictions on transfer of CBI from FDA. Petitioners should request FDA to transfer petitions and FDA evaluations to EPA. Such requests should be directed to the FDA consumer safety officer (CSO) named in the filing notice of the petition or current CSO, if changed since the filing notice. FDA will not transfer any petition or FDA evaluations to EPA until FDA has a signed consent form from the petitioner to transfer such records. FDA will provide the consent form to the petitioner after receiving the petitioner's request for a transfer of records to EPA.

Once FDA has transferred a petition and associated files to EPA, EPA will review the petition. However, companies will need to take some additional steps to allow EPA to complete its review of the petition. First, each petitioner must prepare a short summary of its petition and the data, information, and argument submitted in support of the petition. Second, each petitioner must address the specific factors EPA is required by FFDCA to consider as part of its determination of whether the safety standard in FFDCA section 408 is met. Both of these points were discussed in detail under the "New Petitions," section in this unit.

EPA recognizes that the uncertainty about the jurisdiction of FDA and EPA under FFDCA over antimicrobial agents has caused delays in issuing final decisions on some of the pending petitions. EPA is taking several steps to lessen the impact of such delay. First, EPA will not require the submission of a new petition for any chemical which is the subject of a petition pending with FDA. Instead, EPA will accept the petition as it was submitted to FDA and will process it without further delay. Second, for pending petitions, EPA will waive the required tolerance fee required under FFDCA section 408(m). EPA has the authority to waive or reduce the tolerance fee when waiving the payment of the fee would be "equitable and not contrary to the purposes of this subsection" (FFDCA section 408(m)(1)). In this instance, EPA believes that it would be equitable to waive the required fee because it partially offsets any financial burdens resulting from the delay in taking final action on pending petitions. Finally, as noted earlier, completion of review of these petitions holds a very high priority at EPA.

C. EPA-Registered Products Which Would Cease to Be "Pesticides" Under FIFRA Pursuant to the Proposed Rulemaking

As discussed in Unit III. of this notice, EPA and FDA have agreed that EPA will propose a rule amending the definition of "pest" in 40 CFR 152.5(d). If that rule becomes final, certain antimicrobial substances would no longer be "pesticides" and

would no longer be subject to regulation under FIFRA. On the effective date of such a final rule, EPA would discontinue registration of any products, previously registered by EPA as pesticides, and bearing labeling for use only against microorganisms that would not be pests.

Former registrants of such products should note that the Federal decision regarding what is a pesticide may not be definitive for the purposes of state regulatory schemes. Former registrants are encouraged to contact state officials to determine how such an EPA rulemaking would affect a product's regulatory status under state law.

EPA would continue to require registration for antimicrobial substances that continue to be "pesticides" under FIFRA, even though certain uses for such substances would be "food additive" uses under FFDCA. Consistent with current EPA practice, when the use of an antimicrobial substance is both a food additive and a pesticide use as, for example, a slimicide used in the production of food and non-food-contact paper, EPA would review labeling for the pesticidal use and FDA would review the non-pesticidal, i.e., food additive, use. Such a substance may be categorically excluded from the need for an environmental assessment under FDA's regulations implementing the National Environmental Policy Act (NEPA) based on the fact that the food additive use is substantially identical to the pesticide use (62 FR 40570, 40596; July 29, 1997 (citing to the categorical exclusion in 21 CFR 25.32(q))). After FDA approves a food additive that is also regulated as a FIFRA "pesticide," a petitioner would need to formally request EPA to amend its pesticide registration label for the antimicrobial to include the "non-pesticidal" use.

VI. Agency Contacts

In the event of questions about the process, EPA and FDA staff are available to meet with petitioners to discuss the status of pending petitions and procedures for submitting a new petition. If a petitioner or any other person considering submitting a petition is interested in meeting with either agency, he or she should contact the ***54544** appropriate Branch Chief in EPA's Antimicrobials Division to schedule a meeting or the appropriate team leader in FDA's Indirect Additives Branch.

The EPA Branch Chiefs can be reached at:

Dennis Edwards, Chief, Regulatory Management Branch I, Antimicrobials Division (7510W), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (703) 308-8087, Fax: (703) 308-8481, e-mail: edwards.dennis@epamail.epa.gov.

Connie Welch, Chief, Regulatory Management Branch II, Antimicrobials Division (7510W), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (703) 308-8218, Fax: (703) 308-6466, e-mail: welch.connie@epamail.epa.gov.

FDA can be contacted at:

Sandra L. Varner or Andrew J. Zajac, Office of Pre-market Approval Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St., SW., Washington, DC 20204-0002, Telephone: (202) 418-3075 (S. Varner) (202), 418-3095 (A. Zajac).

Mark A. Hepp, Office of Pre-Market Approval Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St., SW., Washington, DC 20204-0002, Telephone: (202) 418-3098.

VII. EPA Public Record and Electronic Submissions

The EPA official record for this notice, as well as the public version, has been established for this document under docket control number "OPP-300624" (including comments and data submitted electronically as described below). A public version

of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the Virginia address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number "OPP-300624." Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental Protection Agency, Food and Drug Administration, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 30, 1998.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances, Environmental Protection Agency.

Dated: August 21, 1998.

Sharon Smith Holston,

Acting Commissioner, Food and Drug Administration.

[FR Doc. 98-27261 Filed 10-8-98; 8:45 am]

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APPENDIX G

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2009 RED BOOK

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How to Find an Rx Product

The layout of *Red Book*® product listings allows for easy identification of Rx products, manufacturer names, generic cross-references, and repackagers of pharmaceutical products. It also identifies Federal Upper Limit prices for Medicaid reimbursement from the Centers for Medicare and Medicaid Services (CMS). Products are listed alphabetically by their prevailing names, as explained below. (For information on how to locate and interpret OTC and non-drug product listings, refer to Section 10.)

Product quantities appear in National Council for Prescription Drug Programs (NCPDP) standard billing units (e.g., ea, ml, gm). Please see Section 6, "Drug Reimbursement Information," for information on the NCPDP standard. A conversion table can be found in Section 2, "Clinical Reference Guide."

Trademarked Name: For branded products, detailed information is found under the brand name rather than the generic name; e.g., "Valium" product information is listed under "Valium" rather than under diazepam. However, you will find a cross-reference under Roche Labs, the manufacturer of Valium, in the diazepam listing.

VALIUM (Roche Labs)
diazepam
TAB, PO, 10 mg,
100s ea, C-IV ..... 00140-0806-01 286.12 AB

Generic Name: In-depth product information on generic products can be found by locating the generic product name, under which the various manufacturers, suppliers, or distributors are listed alphabetically, e.g., diazepam features several dozen generic manufacturers. Manufacturers listed under their trademarked product name feature a cross-reference to that name.

DIAZEPAM
[redacted]
TAB, PO, 2 mg, 100s ea 2.09
(Hospira, Inc)
INJ, IJ (AMP)
5 mg/ml,
2 ml 10s, C-IV ..... 00674-1273-32 25.29 AP
(Roche Labs) *See VALIUM*

Single-ingredient generic names are spelled out in full. Multi-ingredient products (two or more) are listed in the alphabetical order of their ingredients using the standard abbreviations listed on the following pages.

Drug Class Symbols

The following descriptive symbols indicate a product's status under the Controlled Substances Act of 1970. They apply to all entries under the product name or dosage form in which they appear. Use these symbols only as a guide. Check the manufacturer's label for definitive information.

C-II	High Potential for Abuse. Prescriptions must be written in ink or typewritten and signed by the practitioner. Verbal prescriptions must be confirmed in writing within 72 hours and may be given only in a genuine emergency. No renewals.
C-III	Some Potential for Abuse. Prescriptions may be oral or written. Up to 5 renewals are permitted within 6 months.
C-IV	Low Potential for Abuse. Prescriptions may be oral or written. Up to 5 renewals are permitted within 6 months.
C-V	Subject to State and Local Regulation. Abuse potential is low; a prescription may not be required.
Rx	Prescription only; not a controlled substance.

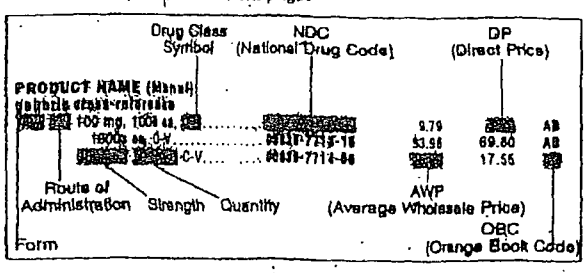
How to Read the Listings

The first line of an entry features the product or generic name. CMS Federal Upper Limit price information is provided for all applicable multisource product categories. The [redacted] symbol can be found immediately following the generic product name. A complete listing of Federal Upper Limit prices appears in Section 6, "Drug Reimbursement Information."

Manufacturers are listed alphabetically within generic listings. Repackagers of products feature the [redacted] symbol next to their names. For trade name listings, generic cross-references appear in lower case on the following line.

A three-letter abbreviation indicates the form of the drug; e.g., CAP indicates capsules, TAB indicates tablets, etc. For a key to additional abbreviations, refer to the table on the following page.

Route of administration, descriptive information, strength, quantity, and drug class symbol (where applicable) appear next, followed by National Drug Code (NDC) number. The Average Wholesale Price (AWP), Direct Price (DP), and the Orange Book Code (OBC) complete the entry for each product. For more information on Orange Book Codes, refer to the next page.



The prices contained in *Red Book* are based on data *reported* by manufacturers. The publisher has not performed any independent analysis of the *actual* prices paid by wholesalers and providers in the marketplace. Thus, actual prices paid by wholesalers and providers may well vary from the prices contained in this publication and all prices are subject to change without notice. Further, while care has been exercised in compiling all of the information contained herein, the publisher does not warrant its accuracy. For further explanation, see the section titled "AWP Policy" in the *Red Book* Foreword. Information may be supplemented by subscribing to the monthly *Red Book UPDATE*®, ReadyPrice™, *Red Book* for Windows™, *Red Book* data services, or by obtaining prices published in catalogs or other printed materials disseminated by manufacturers or distributors.

ROUTE OF ADMINISTRATION ABBREVIATIONS

Route of Administration (ROA) refers to the intake or application method of a product. The following abbreviations are used to indicate the ROA:

BC	Buccal
DE	Dental
EP	Epidural
IC	Intracavernosal
ID	Intradermal
IH	Inhalation
IJ	Injection
IL	Intravesical
IM	Intramuscular
IN	Intrathecal
IO	Intraocular
IP	Implantation
IR	Irrigation
IT	Intratracheal
IU	Intrauterine
IV	Intravenous
MM	Mucous membrane
MR	Multiple routes
NA	Not applicable
NS	Nasal
OP	Ophthalmic
OT	Otic
PL	Intrapleural
PO	Oral
PT	Intraperitoneal
RC	Rectal
SC	Subcutaneous
SG	Subgingival
SL	Sublingual
TD	Transdermal
TP	Topical
UR	Intraurethral
VG	Vaginal

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ORANGE BOOK CODES

The Orange Book Codes supply the FDA's therapeutic equivalence rating for applicable multisource categories. Codes beginning with "A" signify that the product is deemed therapeutically equivalent to the reference product for the category. Codes beginning with "B" indicate that bioequivalence has not been confirmed. In certain instances, a number is added to the end of the AB code to make it a three-character code (i.e., AB1, AB2, AB3, etc.). Three-character codes are assigned only in situations where more than one reference drug of the same strength has been designated under the same heading. "EE" is assigned by *Red Book* to products that have been evaluated by the FDA but for which an equivalence rating is not available.

Products appearing in the Orange Book have historically been limited to those manufacturers holding the original approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA). However, in recognition of the fact that generic products are available from a widespread number of sources, *Red Book* publications and database services extend Orange Book ratings to distributors and generic labelers other than the holder of the NDA or ANDA. All ratings applied to such labelers have been directly supplied to *Red Book* through written certification attesting to the accuracy of the codes supplied.

- AA.....No bioequivalence problems in conventional dosage forms
- AB.....Meets bioequivalence requirements
- AB1.....Meets bioequivalence requirements to AB1 rated reference drug
- AB2.....Meets bioequivalence requirements to AB2 rated reference drug
- AB3.....Meets bioequivalence requirements to AB3 rated reference drug
- AN.....Solution or powder for aerosolization
- AO.....Injectable oil solution
- AP.....Injectable aqueous solution
- AT.....Topical product
- BC.....Controlled-release tablet, capsule, or injectable
- BD.....Documented bioequivalence problem
- BN.....Product in aerosol-nebulizer delivery system
- BP.....Potential bioequivalence problem
- BR.....Suppository or enema for systemic use
- BS.....Testing standards are insufficient for determination
- BT.....Topical product with bioequivalence issues
- BX.....Insufficient data to confirm therapeutic equivalence
- EE.....This entry has been evaluated by the FDA, but a rating is not available for this labeler's product

OTHER DESCRIPTIVE ABBREVIATIONS

The following abbreviations are used to provide additional descriptive information about products:

- A.F.....Alcohol-free
- AMP.....Ampule
- D.F.....Dye-free
- EXT. STR.....Extra strength
- F.C.....Film coated
- F.F.....Fragrance-free
- FR.....French
- INSTIT. USE.....Institutional use
- MAX. STR.....Maximum strength
- M.D.V.....Multi-dose vial
- N.F.....National Formulary
- P.B.....Piggyback
- P.C.....Plastic container
- P.F.....Preservative-free
- R.N.P.....Reversed number package
- S.D.....Single dose
- S.D.V.....Single-dose vial
- S.F.....Sugar-free
- SRN.....Syringe
- TAX INCL.....Federal excise tax included
- U.D.....Unit dose
- U.S.P.....U.S. Pharmacopeia

STANDARD DOSAGE FORM DESCRIPTIONS

The following three-character abbreviations are used to indicate form in which a product is available:

ACC	Accesory
AER	Aerosol liquid
ARO	Aerosol powder
BAN	Bandage
BAR	Bar
BEA	Beads
C12	Capsule, extended release, 12-hr.
C24	Capsule, extended release, 24-hr.
CAK	Cake
CAP	Capsule
CER	Capsule, extended release
CHI	Chip
CRE	Cream
CRY	Crystal
CTB	Tablet, chewable
DAP	Patch, device assisted
DEV	Device
DRE	Dressing
DSK	Disk
ECC	Capsule, delayed release
ECT	Tablet, enteric-coated
ELI	Elixir
EMO	Emollient cream
EMU	Emulsion
FIL	Film
FLA	Flake
FOA	Foam
GAS	Gas
GEF	Powder, effervescent
GEL	Gel/jelly
GER	Granules, extended release
GFS	Gel-forming solution
GRA	Granules
GUM	Gum
ICR	Insert, extended release
IMP	Implant
INJ	Injection
KIT	Kit
LEA	Leaf
LIQ	Liquid
LOT	Lotion
LOZ	Lozenge/troche
LUM	Lump
NMA	Enema
ODT	Tablet, disintegrating
OEM	Emollient ointment
OIL	Oil
OIN	Ointment
PAD	Pad
PAS	Paste
PDR	Powder for suspension
PDS	Powder for solution
PEL	Pellet
PI1	Powder for suspension, 1-month
PI3	Powder for suspension, 3-month
PI4	Powder for suspension, 4-month
PI6	Powder for suspension, 6-month
PKT	Packet
POD	Pod
POW	Powder
PRO	Prophylactic
PUD	Pudding
SER	Suspension, extended release
SGL	Capsule, liquid-filled
SHA	Shampoo
SHE	Sheet
SOA	Soap
SOL	Solution
SPE	Suppository, extended release
SPG	Sponge
SPR	Spray
STI	Stick
SUP	Suppository
SUS	Suspension
SWA	Swab
SYR	Syrup
T12	Tablet, extended release, 12-hr.
T24	Tablet, extended release, 24-hr.
TAB	Tablet
TAM	Tampon
TAP	Tape
TBS	Tablet for suspension
TCP	Tablet, coated particles
TDM	Patch, extended release
TDR	Tablet disintegrating, delayed
TEF	Tablet, effervescent
TER	Tablet, extended release
TES	Test
TIN	Tincture
TSR	Tablet for solution
WAF	Wafer
WAX	Wax

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ABBREVIATED INGREDIENT DESCRIPTIONS

Generic names are listed according to the following guidelines:

- Single-ingredient generic names will be spelled out in full (e.g., ACETAMINOPHEN)
- Multi-ingredient products (two or more) are listed in the alphabetical order of their ingredients using the following standard abbreviations:

ACE	ACETATE
ALK	ALKALOIDS
APAP	ACETAMINOPHEN
ASA	ASPIRIN
BELL	BELLADONNA
BENZO	BENZOCAINE
BICARB	BICARBONATE
BIT	BITARTRATE
BPM	BROMPHENIRAMINE
CA	CALCIUM
CAFF	CAFFEINE
CIT	CITRATE
CL	CHLORIDE
CPM	CHLORPHENIRAMINE
CR	CHROMIUM
CU	COPPER
DM	DEXTROMETHORPHAN
DSS	DOCUSATE SODIUM
EPH	EPHEDRINE
EPI	EPINEPHRINE
FE	IRON
FUM	FUMARATE
GG	GUAIFENESIN
HC	HYDROCORTISONE
HCL	HYDROCHLORIDE
HCTZ	HYDROCHLOROTHIAZIDE
HEP	HEPATITIS
HYDROBROM	HYDROBROMIDE
HYDROCOD	HYDROCODONE
IF	INTRINSIC FACTOR
K	POTASSIUM
GUAI	GUAIACOLSULFONATE
KI	POTASSIUM IODIDE
LACT	LACTATE
MAL	MALEATE
MG	MAGNESIUM
MN	MANGANESE
NA	SODIUM
PB	PHENOBARBITAL
PEG	POLYETHYLENE GLYCOL
PENTOBARB	PENTOBARBITAL
PHENYLEPH	PHENYLEPHRINE
PHOS	PHOSPHATE
PPA	PHENYLPROPANOLAMINE
PSE	PSEUDOEPHEDRINE
PYRIL	PYRILAMINE
SCOP	SCOPOLAMINE
SE	SELENIUM
SULF	SULFATE
TAN	TANNATE
TART	TARTRATE
THEOPH	THEOPHYLLINE
VAC	VACCINE
VIT	VITAMIN
ZN	ZINC

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(Kaiser Pharms., Inc.)
HYDROCORTISONE
CRE, TP (1X30GM)
0.05%, 30 gm..... 68387-0827-01 26.50 AB

(Mucos Pharm)
HYDROCORTISONE
CRE, TP, 0.05%, 15 gm.... 68267-0973-15 24.19 EE

(Palmetto)
HYDROCORTISONE
CRE, TP, 0.05%, 15 gm.... 23490-5588-01 25.36
30 gm.... 23490-5588-02 46.65
(1X60GM)
0.05%, 60 gm.... 23490-5588-03 77.99

(Pharma Pac)
HYDROCORTISONE
CRE, TP, 0.05%, 15 gm.... 52959-0001-01 25.36 EE
15 gm.... 52959-0299-05 15.66 AB
30 gm.... 52959-0002-03 30.35 EE
30 gm.... 52959-0299-30 29.32 AB
60 gm.... 52959-0003-02 48.98 EE
60 gm.... 52959-0299-60 51.85 AB
GEL, TP, 0.05%, 60 gm.... 52959-0002-66 60.50 AB
OIN, TP, 0.05%, 15 gm.... 52959-0316-01 22.15 EE
30 gm.... 52959-0315-03 46.65 EE

(Phys Total Care)
HYDROCORTISONE
CRE, TP, 0.05%, 15 gm.... 54868-0431-02 6.48 EE
30 gm.... 54868-0431-03 8.16 EE
60 gm.... 54868-0431-01 11.34 EE
GEL, TP, 0.05%, 60 gm.... 54868-3021-00 44.25 AB
OIN, TP (1X15GM)
0.05%, 15 gm.... 54868-3435-02 21.46 AB
30 gm.... 54868-3435-00 42.21 EE
60 gm.... 54868-3435-01 80.88 EE
SOL, TP, 0.05%, 60 ml.... 54868-2451-01 25.11 EE

(Physician Partner)
HYDROCORTISONE
EMO, TP, 0.05%, 15 gm.... 21895-0287-15 38.80 AB
60 gm.... 21895-0287-60 90.12 AB

(Quality Care Prod)
HYDROCORTISONE
CRE, TP, 0.05%, 15 gm.... 40989-0172-15 28.98 AB
30 gm.... 40989-0172-30 57.96 AB

(Southwood)
HYDROCORTISONE
CRE, TP, 0.05%, 15 gm.... 58016-3642-01 23.29 EE
30 gm.... 58016-3121-01 24.90 EE
GEL, TP, 0.05%, 15 gm.... 58016-4879-01 21.01 EE
60 gm.... 58016-3274-01 52.55 EE

(Stat Rx)
HYDROCORTISONE
CRE, TP, 0.05%, 15 gm.... 16590-0368-15 24.00 AB
30 gm.... 16590-0368-30 22.00 AB
(1X30GM)
0.05%, 30 gm.... 16590-0368-39 7.00 AB
60 gm.... 16590-0368-60 29.00 AB
(1X60GM)
0.05%, 60 gm.... 16590-0368-80 14.00 AB

FLUOCINONIDE E (Taro)
fluocinonide
EMO, TP (EMULSIFIED BASE)
0.05%, 15 gm.... 51672-1254-01 19.40 AB
30 gm.... 51672-1254-02 28.88 AB
60 gm.... 51672-1254-03 45.08 AB

(Teva)
EMO, TP (EMULSIFIED BASE)
0.05%, 15 gm.... 00093-0263-15 19.90 AB
30 gm.... 00093-0263-30 27.50 AB
60 gm.... 00093-0263-92 46.00 AB

(Phys Total Care)
HYDROCORTISONE
EMO, TP, 0.05%, 30 gm.... 54868-3408-00 28.59 EE
60 gm.... 54868-3408-01 49.96 EE

(Physician Partner)
HYDROCORTISONE
EMO, TP, 0.05%, 30 gm.... 21895-0287-30 77.60 AB

FLUOCINONIDE MICRONIZED (PCCA)
fluocinonide, micronized
POW, NA (USP, 1X1GM)
1 gm.... 51927-1618-00 78.00

FLUOCINONIDE, MICRONIZED
(PCCA) See FLUOCINONIDE MICRONIZED

FLUONAZOLE (Teva)
fluconazole
FOR, PO (1X35ML,ORANGE)
10 mg/ml, 35 ml.... 00093-5414-35 36.46
40 mg/ml, 35 ml.... 00093-5415-35 132.45

FLUOR-A-DAY (Pharmascience Labs)
sodium fluoride
CTB, PO (SF,RASPBERRY)
0.25 mg, 120s ea.... 51817-0622-15 7.02
0.5 mg, 120s ea.... 51817-0611-15 7.02
1 mg, 120s ea.... 51817-0622-15 7.02
LIQ, PO (DROPS)
0.125 mg/drp,
30 ml.... 51817-0656-01 5.81

FLUOR-I-STRIP A.T. (Bausch & Lomb Inc.)
fluorescein sodium
TES, OP (STRIP)
1 mg, 300s ea. 24208-0391-33 77.80

(Phys Total Care)
HYDROCORTISONE
TES, OP, 1-mg, 300s ea. 54868-5127-00 98.00

FLUORABON (Perry Med)
sodium fluoride
CTB, PO (ORANGE)
1 mg, 100s ea 11783-0526-01 2.31
100s ea.. 11783-0526-01 2.31
LIQ, PO (DROPS)
0.25 mg/0.6 ml,
60 ml.. 11783-0524-20 3.08

FLUORACAINE (Akorn)
fluorescein sodium/proparacaine hydrochloride
SOL, OP (GLASS BOTTLE)
0.25%-0.5%, 5 ml .. 17478-0328-10 9.15

FLUORES/BENOX (Phys Total Care)
HYDROCORTISONE
benzocaine hydrochloride/fluorescein sodium
SOL, OP, 0.4%-0.25%,
5 ml.... 54868-3957-00 37.41

FLUORESCEIN (HUB Pharma)
fluorescein sodium
SOL, IV (SDV,5MLX12,USP,STERILE)
10%, 5 ml 12s.... 17238-0301-05 58.25
(SDV,2MLX12,USP,STERILE)
25%, 2 ml 12s.... 17238-0401-02 56.25

FLUORESCEIN (PCCA)
POW, NA (C.I. 45350)
1 gm.... 51927-1852-00 0.78

FLUORESCEIN LITE (Altaire)
fluorescein sodium
SOL, IV (S.D.V.)
10%, 5 ml.. 59390-0188-05 4.68
25%, 2 ml.. 59390-0187-02 4.68

FLUORESCEIN SODIUM
(Akorn) See AK-FLUOR

(Akorn) See FUL-GLO

(Alcon Ophthalmic) See FLUORESCITE

(Altaire) See FLUORESCEIN LITE

(Altaire)
SOL, IV (SDV,12X5ML)
10%, 5 ml 12s 59390-0188-05 7.80
(SDV,12X2ML)
25%, 2 ml 12s 59390-0200-02 7.80

(Bausch & Lomb Inc.) See FLUOR-I-STRIP A.T

(Bausch & Lomb Inc.) See FLUORETS

(Eyesupply USA) See ANGIOSCEIN

(Gallipot)
POW, NA (USP,1X25GM)
25 gm.... 51552-0388-04 15.05 10.75
(USP,1X100GM)
100 gm 51552-0388-06 38.50 27.50

(HUB Pharma) See BID GLO

(HUB Pharma) See FLUORESCEIN

(PCCA)
POW, NA (U.S.P)
1 gm 51927-1881-00 0.98

(Spectrum Pharmacy)
POW, NA (U.S.P.)
25 gm.. 49452-3100-02 45.85
100 gm.... 49452-3100-01 98.88
1000 gm.... 49452-3100-02 623.70

FLUORESCEIN SODIUM
AND BENOXINATE HYDROCHLORIDE (HUB Pharma)
benoxinate hydrochloride/fluorescein sodium
SOL, OP (DROPS)
0.4%-0.25%, 5 ml.... 17238-0501-05 8.19

FLUORESCEIN SODIUM/
PROPARACAINE HYDROCHLORIDE
(Akorn) See FLUORACAINE

(Altaire) See FLUOROCAINE SOD/PROPARACAINE HCL

(Dexsun) See FLUCAINE

FLUORESCEIN/BENOXINATE (OHS, Inc.)
HYDROCORTISONE
benoxinate hydrochloride/fluorescein sodium
SOL, OP, 0.4%-0.25%,
5 ml.... 55887-0778-05 14.75

(Southwood)
HYDROCORTISONE
SOL, OP, 0.4%-0.25%,
5 ml. 58016-4994-01 11.81

FLUORESCITE (Alcon Ophthalmic)
fluorescein sodium
SOL, IV (AMP)
10%, 5 ml.. 00065-0092-05 29.94

FLUORETS (Bausch & Lomb Inc.)
fluorescein sodium
TES, OP (STRIP)
1 mg, 100s ea. 24208-0391-82 22.97

(Quality Care Prod)
HYDROCORTISONE
TES, OP, 1 mg, 100s ea 35356-0179-00 56.40

FLUORI-METHANE (Phys Total Care)
HYDROCORTISONE
dichlorodifluoromethane/trichlorofluoromethane
SPR, TP (RRE)
15%-85%, 103 ml.... 54868-4156-00 39.30

FLUORIDE (Cypress Pharm)
sodium fluoride
CTB, PO (SF,SACCHARIN-FREE,LEMON)
0.25 mg, 120s ea.... 68258-0155-20 6.65
(SF,SACCHARIN-FREE,GRAPE)
0.5 mg, 120s ea.. 68258-0158-20 8.89
1000s ea.. 68258-0158-10 55.44
1 mg, 120s ea.. 68258-0157-20 8.65

FLUORINSE (Oral B Lab)
sodium fluoride
SOL, PO (AF,CINNAMON)
0.2%, 480 ml 00061-0351-07 7.49
(AF,MINT)
0.2%, 480 ml. 00061-0356-07 7.49

FLUORITAB (Fluoritab)
sodium fluoride
CTB, PO (CHERRY)
0.5 mg, 100s ea.. 00268-1106-01 2.16
1000s ea.. 00268-1106-10 12.56
5000s ea.. 00268-1106-02 38.00
1 mg, 100s ea.. 00268-2264-01 2.16
1000s ea.. 00268-2263-10 12.66
5000s ea.. 00268-2263-02 38.00
LIQ, PO (DYE-FREE,DROPS)
0.25 mg/drp, 23 ml. 00268-8523-23 2.16

FLUORO/GLY GEL (Topix)
glycolic acid
GEL, TP (OFFICE USE ONLY)
120 gm.. 51328-0025-04 15.00
120 gm.... 51328-0027-04 25.00
120 gm.... 51328-0029-04 35.00

FLUORO/GLY PADS (Topix)
glycolic acid
PAD, TP (OFFICE USE ONLY)
30s ea.. 51328-0006-30 30.00
30s ea.. 51328-0008-30 50.00
30s ea.. 51328-0010-30 70.00

FLUOROCAINE SOD/PROPARACAINE HCL (Altaire)
fluorescein sodium/proparacaine hydrochloride
SOL, OP (STERILE)
0.25%-0.5%, 5 ml 59390-0265-05 9.15

FLUOROMETHOLONE
(Allergan Inc) See FML FORTE LIQUIFILM

(Allergan Inc) See FML LIQUIFILM

(Allergan Inc) See FML S.O.P.

(Bausch & Lomb Inc.)
SUS, OP, 0.1%, 5 ml.... 24208-0280-05 15.80
10 ml.... 24208-0280-10 26.16
15 ml.... 24208-0280-15 35.18

(Pacific Pharma)
SUS, OP, 0.1%, 5 ml.... 60758-0858-05 10.05 AB
10 ml.... 60758-0858-10 16.01 AB
15 ml.... 60758-0858-15 22.39 AB

(PCCA)
POW, NA (U.S.P.)
gm.... 51927-2272-00 2.18

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LOZOL (Phys Total Care)
REPACKER
nizapamide
TAB, PO, 2.5 mg, 30s ea... 54868-1295-01 41.57 AB

LTA PEDIATRIC (Abbott Hosp)
lidocaine hydrochloride
KIT, MM (LATEX-FREE)
2%, 24s ea ..... 00074-5648-01 233.57 233.52 AT

LTA PREATTACHED (Hospira)
lidocaine hydrochloride
KIT, MM, 4%, 25s ea... 00409-4898-01 114.60 125.50 AT

LUBIPROSTONE
(Takeda) *See AMITIZA*

LUCENTIS (Genentech)
ranibizumab
SOL, IO (INTRAVITREAL INJECTION)
0.5 mg/0.05 ml,
0.05 ml ... 50242-0098-01 2437.50

LUFYLLIN (Meda)
dyphylline
TAB, PO, 200 mg, 100s ea. 00037-0521-01 294.22 BP

LUFYLLIN-400 (Meda)
dyphylline
TAB, PO, 400 mg, 100s ea. 00037-0731-01 432.04 BP

LUFYLLIN-GG (Meda)
dyphylline/guaifenesin
ELI, PO, 480 ml 00037-0546-60 256.77

LUGOL'S SOLUTION (Humco)
iodine/potassium iodide
SOL, NA, 480 ml ... 00395-2775-16 16.56

(Medisca)
SOL, NA, 500 ml 38779-0508-08 48.00

(PCCA)
SOL, NA (USP)
1 ml. ... 51927-1547-00 0.17

(Salsoor)
SOL, NA, 15 ml... 48433-0230-15 21.12 17.60

LUGOL'S STRONG IODINE (Cooper Surgical)
iodine/potassium iodide
SOL, TP (12-5ML VIALS,PF)
5%-10%, 5 ml 12s ... 59385-0001-01 74.98

LUMBAR PUNCTURE TRAY (Portex)
lidocaine hydrochloride
KIT, IJ (ADULT,20G,3-1/2"QUINCKE)
1%, 10s ea ... 0007-4-4824-20 390.81 329.10
(ADULT,22G,3-1/2"QUINCKE)
1%, 10s ea ... 0007-4-4825-20 390.81 329.10

LUMIGAN (Allergan Inc)
bimatoprost
SOL, OP, 0.03%, 2.5 ml ... 00023-9187-03 80.53
5 ml. ... 00023-9187-05 161.02
7.5 ml ... 00023-9187-07 241.52

(DispenseXpress)
REPACKER
SOL, OP, 0.03%, 2.5 ml ... 12280-0382-25 130.60
5 ml. ... 12280-0382-05 253.44

(Phys Total Care)
REPACKER
SOL, OP, 0.03%, 3 ml ... 54868-4575-02 102.91
5 ml. ... 54868-4575-00 176.43
7.5 ml ... 54868-4575-01 273.61

(Quality Care Prod)
REPACKER
SOL, OP (1X2.5ML,DROP)
0.03%, 2.5 ml. ... 35356-0405-25 155.48

LUMINAL SODIUM (Hospira)
phenobarbital sodium
SOL, IJ (LUER LOCK,10X1ML)
60 mg/ml,
1 ml 10s, C-IV ... 00409-2343-31 34.32 30.00
(LUER LOCK,CARPUJECT)
130 mg/ml,
1 ml 10s, C-IV ... 00409-2648-31 44.78 39.20

LUNESTA (Sepracor)
eszopiclone
TAB, PO (FILM-COATED)
1 mg, 30s ea, C-IV... 63402-0198-30 166.88
100s ea, C-IV ... 63402-0198-10 555.80
2 mg, 90s ea, C-IV... 63402-0199-90 455.76
100s ea, C-IV ... 63402-0199-10 505.80
3 mg, 90s ea, C-IV... 63402-0193-90 455.76
100s ea, C-IV ... 63402-0193-10 505.80

(Allscripts)
REPACKER
TAB, PO (FILM-COATED)
2 mg, 30s ea, C-IV... 54569-5606-00 173.63
3 mg, 30s ea, C-IV... 54569-5604-00 173.63

(Altura)
REPACKER
TAB, PO, 1 mg,
30s ea, C-IV... 63874-1152-03 133.36
(FILM-COATED)
3 mg, 30s ea, C-IV ... 63874-1153-03 133.36

(Bryant Ranch)
REPACKER
TAB, PO, 3 mg,
30s ea, C-IV 63629-3142-01 132.90

(Cara)
REPACKER
TAB, PO, 3 mg,
30s ea, C-IV ... 33358-0227-30 126.94

(DispenseXpress)
REPACKER
TAB, PO (FILM-COATED)
1 mg, 30s ea, C-IV ... 12280-0180-30 233.42
2 mg, 15s ea, C-IV... 12280-0287-15 140.72
30s ea, C-IV ... 12280-0287-30 233.19
(FILM-COATED)
3 mg, 30s ea, C-IV. 12280-0179-30 233.19
90s ea, C-IV. 12280-0179-90 884.19

(DRX)
REPACKER
TAB, PO, 2 mg,
30s ea, C-IV.... 55045-3481-01 150.00
3 mg, 30s ea, C-IV... 55045-3482-01 150.00

(IPR)
REPACKER
TAB, PO, 2 mg,
30s ea, C-IV. ... 18837-0080-30 190.98
3 mg, 30s ea, C-IV ... 18837-0081-30 190.99
60s ea, C-IV... ... 18837-0081-60 361.98
90s ea, C-IV... ... 18837-0081-90 572.96

(Kallman Pharma., Inc.)
REPACKER
TAB, PO, 3 mg,
30s ea, C-IV ... 66267-0487-30 151.00

(PD-Rx Pharm)
REPACKER
TAB, PO (FILM-COATED)
3 mg, 30s ea, C-IV... 55289-0014-30 226.97

(Pharma Pac)
REPACKER
TAB, PO, 2 mg,
100s ea, C-IV ... 52959-0018-00 405.10
3 mg, 10s ea, C-IV. ... 52959-0052-10 53.80
12s ea, C-IV... ... 52959-0052-12 64.56
30s ea, C-IV... ... 52959-0052-30 146.13
100s ea, C-IV ... 52959-0052-00 537.99

(Phys Total Care)
REPACKER
TAB, PO, 1 mg,
20s ea, C-IV... ... 54868-5439-01 124.38
(FILM-COATED)
1 mg, 60s ea, C-IV... 54868-5439-00 348.80
2 mg, 10s ea, C-IV... 54868-5273-01 71.60
20s ea, C-IV... ... 54868-5273-02 141.89
(FILM-COATED)
2 mg, 30s ea, C-IV ... 54868-5273-00 199.82
3 mg, 10s ea, C-IV ... 54868-5394-04 72.25
15s ea, C-IV... ... 54868-5394-02 107.07
(FILM-COATED)
3 mg, 30s ea, C-IV ... 54868-5394-01 200.56

(Physician Partner)
REPACKER
TAB, PO, 2 mg,
30s ea, C-IV. ... 21695-0225-30 347.25
3 mg, 15s ea, C-IV... 21695-0226-15 169.41
30s ea, C-IV... ... 21695-0226-30 347.25

(Quality Care Prod)
REPACKER
TAB, PO (FILM-COATED)
1 mg, 30s ea, C-IV... 49999-0778-30 133.37
2 mg, 15s ea, C-IV... 49999-0779-15 177.66
30s ea, C-IV... ... 49999-0779-30 323.00
(FILM-COATED)
3 mg, 14s ea, C-IV... 49999-0737-14 166.81
15s ea, C-IV... ... 49999-0737-15 177.65
30s ea, C-IV... ... 49999-0737-30 326.00
60s ea, C-IV... ... 49999-0737-60 648.00
90s ea, C-IV... ... 49999-0737-90 969.00

(FILM-COATED)
3 mg,
100s ea, C-IV ... 49999-0737-00 866.83

(Southwood)
REPACKER
TAB, PO, 2 mg,
30s ea, C-IV... 58016-0040-30 121.14
60s ea, C-IV... 58016-0040-60 242.28
90s ea, C-IV... 58016-0040-90 363.42
100s ea, C-IV... 58016-0040-00 403.80
3 mg, 30s ea, C-IV... 58016-0292-30 111.14
60s ea, C-IV... 58016-0292-60 222.28
90s ea, C-IV... 58016-0292-90 333.42
100s ea, C-IV ... 58016-0292-00 370.47

(St. Mary's MPP)
REPACKER
TAB, PO (FILM-COATED)
3 mg, 30s ea, C-IV... 60760-0183-30 286.44

(Stat Rx)
REPACKER
TAB, PO, 1 mg,
30s ea, C-IV... 16590-0502-30 141.78
(FILM-COATED)
1 mg, 60s ea, C-IV... 16590-0502-60 391.31
90s ea, C-IV... ... 16590-0502-90 415.50
120s ea, C-IV ... 16590-0502-72 535.00
(FILM-COATED)
2 mg, 25s ea, C-IV... 16590-0501-25 164.49
30s ea, C-IV... ... 16590-0501-30 197.11
60s ea, C-IV... ... 16590-0501-60 283.56
90s ea, C-IV... ... 16590-0501-90 415.50
120s ea, C-IV ... 16590-0501-72 535.00
(FILM-COATED)
3 mg, 25s ea, C-IV... 16590-0503-25 164.49
28s ea, C-IV... ... 16590-0503-28 164.02
30s ea, C-IV... ... 16590-0503-30 210.11
50s ea, C-IV... ... 16590-0503-50 326.37
90s ea, C-IV... ... 16590-0503-90 478.89
120s ea, C-IV ... 16590-0503-72 627.40

LUPRON (Abbott Pharm)
leuprolide acetate
KIT, SC (2 WEEK ADMINISTRATION)
5 mg/ml, ea... 00300-3812-28 594.37 495.31 AP

LUPRON DEPOT (Abbott Pharm)
leuprolide acetate
PI1, IM (SRM,PREFIL DUAL CHAMBER)
3.75 mg, ea... 00300-3841-01 868.28 573.57
7.5 mg, ea... 00300-3842-03 928.21 883.51
PI3, IM, 11.25 mg, ea... 00300-3843-01 2764.85 1720.74
22.5 mg, ea... 00300-3846-01 2580.60 2050.50
PI4, IM, 30 mg, ea... 00300-3843-01 3280.8 12734.01

(Phys Total Care)
REPACKER
PFL, IM, 3.75 mg, ea... 54868-3825-00 885.38
7.5 mg, 1 ml... 54868-3277-00 785.28
PI4, IM, 30 mg, ea... 54868-5364-00 3071.33

LUPRON DEPOT-PED (Abbott Pharm)
leuprolide acetate
PI1, IM (SRM,PREFIL DUAL CHAMBER)
7.5 mg, ea... 00300-3196-01 828.01 690.01
11.25 mg, ea... 00300-3822-01 1503.26 1252.72
(SRM,PREFIL DUAL CHAMBER)
15 mg, ea... 00300-2448-01 1855.61 1379.73

LURIDE (Colgate Oral)
sodium fluoride
CTB, PO (VANILLA)
0.25 mg, 120s ea. 00126-0188-21 7.40
(GRAPE)
0.5 mg, 120s ea... 00126-0814-21 7.40
(CHERRY)
1 mg, 120s ea... 00126-0003-21 7.40
LIQ, PO (W/DROPPER,PEACH,DROPS)
0.5 mg/ml, 50 ml. 00126-0092-62 9.06

(Quality Care Prod)
REPACKER
CTB, PO (GRAPE)
0.5 mg, 30s ea... 49999-0585-30 7.50
(CHERRY)
1 mg, 30s ea... 49999-0568-30 7.25

LUSONA (Wraser Pharm)
phenylephrine hydrochloride
SOL, PO (STRAWBERRY)
7.5 mg/5 ml,
473 ml ... 55992-0146-16 66.01

LUSTRA (Tara)
hydroquinone
CRE, TP, 4%, 56.8 gm... 51672-1328-03 137.40

A-84

(25X40ML,LATEX-FREE)
~~14.6%, 40 ml 25s . . 00409-6610-79 19.30 17.00~~
(VIAL,FLIPTOP,BULK PKG)
23.4%, 100 ml 25s 00409-1141-02 51.60 45.25
250 ml 12s . . 00409-1130-02 49.10 42.96

(Hospira) *See SYREX*

(Lelco)
GRA, NA (U.S.P./N.F.)
1000 gm 62991-1372-02 33.00

(Mallinckrodt Lab)
GRA, NA (U.S.P.)
500 gm 00406-7532-04 17.62
2500 gm 00406-7532-06 52.62

(McGaw) *See SODIUM CHLORIDE BACTERIOSTATIC*

(Medefil) *See NORMAL SALINE FLUSH*

(Medisca)
POW, NA (USP)
100 gm 38779-0629-05 22.50
(U.S.P.)
500 gm 38779-0629-08 31.50
(USP)
1000 gm 38779-0629-09 46.50
2500 gm 38779-0629-01 87.00

(Perl) *See HYPER-SAL*

(PCCA)
GRA, NA (USP)
1 gm 51927-1087-00 0.07

(Sierra) *See NORMAL SALINE IV FLUSH SYRINGE*

(Spectrum Pharmacy)
GRA, NA (U.S.P.)
500 gm. . 49452-6698-01 31.33
2500 gm. 49452-6698-02 79.80
12000 gm 49452-6698-03 248.68
POW, NA, 500 gm. 49452-6706-01 45.33
2500 gm. . 49452-6706-02 125.30

(Vital Signs) *See VASCEZE SODIUM CHLORIDE*

(Allscripts)
REPACK
SOL, IV (AMP)
0.9%, 10 ml 25s 54569-1522-00 21.41 EE

(DRx)
REPACK
SOL, IJ (10MLX25)
0.9%, 10 ml 25s 55045-3718-01 50.00

(Phys Total Care)
REPACK
SOL, IH (AMP,PF)
0.9%, 3 ml 100s 54868-5026-00 50.04
IR (PF,LATEX-FREE)
0.9%, 500 ml 24s 54868-0718-02 91.08 AT
IV (150X5ML)
0.9%, 5 ml 150s 54868-2527-00 90.58
(PF)
0.9%, 10 ml 25s 54868-4464-00 15.95 EE
(20X25ML)
0.9%, 20 ml 25s . . 54868-5714-00 53.76
(NORMAL SALINE,48X50ML)
0.9%, 50 ml 48s . . 54868-0710-05 333.12
(NORMAL SALINE,48X100ML)
0.9%, 100 ml 48s . 54868-0710-03 123.59 EE
(NORMAL SALINE,24X250ML)
0.9%, 250 ml 24s 54868-0710-06 133.96
500 ml . . 54868-0710-01 91.08 EE
1000 ml . . . 54868-0710-00 64.38 EE
(NORMAL SALINE,12X1000ML)
0.9%, 1000 ml 12s 54868-0710-04 83.75

(Southwood)
REPACK
SOL, IJ (10MLX100)
0.9%, 10 ml 100s 58016-4995-01 69.34

SODIUM CHLORIDE BACTERIOSTATIC (Amer Regent)
sodium chloride
SOL, IV (M.D.V.)
0.9%, 30 ml 25s 00517-0648-25 35.94 EE

(Hospira)
SOL, IV (25X10ML, LS-PLASTIC)
0.9%, 10 ml 25s . . . 00409-1966-12 21.60 19.00 AP
(25X10ML,LATEX-FREE)
0.9%, 10 ml 25s . . . . . 00409-1966-04 16.20 14.25 AP
(25X20ML,LATEX-FREE)
0.9%, 20 ml 25s . . . . . 00409-1966-05 21.60 19.00 AP
(FLIPTOP,LS-PLASTIC)
0.9%, 30 ml 25s . . . 00409-1966-14 38.10 33.25 AP
(VIAL,FLIPTOP PLASTIC)
0.9%, 30 ml 25s . . . . 00409-1966-07 16.50 14.50 AP

(McGaw)
SOL, IV (M.D.V.)
0.9%, 30 ml . 49072-0869-30 1.49 EE

(Phys Total Care)
REPACK
SOL, IV (1X750ML,LATEX-FREE)
0.9%, 750 ml 54868-0118-01 74.31 AP

(Quality Care Prod)
REPACK
SOL, IV (1X30ML,LATEX-FREE)
0.9%, 30 ml 35356-0181-30 6.32 AP

SODIUM CHLORIDE CONCENTRATE (Amer Regent)
sodium chloride
SOL, IV (S.D.V.)
23.4%, 30 ml 25s 00517-2930-25 35.94
(BULK PACKAGE)
23.4%, 100 ml 25s 00517-2980-25 93.75

(APP)
SOL, IV (S.D.V.,PF)
23.4%, 30 ml 63323-0187-30 2.39
(MAXIVIAL,BULK PACK,PF)
23.4%, 100 ml . 63323-0088-61 9.30
200 ml 63323-0888-63 17.10

SODIUM CHLORIDE FLUSH (AMSINO)
sodium chloride
SOL, IV (IN 3ML SD SYRINGE,PF)
0.9%, 2.5 ml 180s 68883-0900-01 570.60
(IN 12ML SD SYRINGE,PF)
0.9%, 3 ml 180s . 68883-0900-16 556.20
(IN 6ML SD SYRINGE,PF)
0.9%, 3 ml 180s 68883-0900-03 576.00
(IN 12ML SD SYRINGE,PF)
0.9%, 5 ml 180s 68883-0900-05 649.80
(IN 6ML SD SYRINGE,PF)
0.9%, 5 ml 180s. . 68883-0900-04 586.80
(IN 12ML SD SYRINGE,PF)
0.9%, 10 ml 180s 68883-0900-10 729.00

(Dean Pre-Fld Syr LLC)
SOL, IV (3ML W/CANNULA)
0.9%, 2 ml . . 00409-6611-02 3.70 3.08
(3ML,PRE-FILLED SYRINGE)
0.9%, 2 ml. . 00409-0991-02 2.90 2.42
(6ML W/CANNULA)
0.9%, 3 ml. . 00409-6012-03 3.84 3.20
(6ML,PRE-FILLED SYRINGE)
0.9%, 3 ml. . . 00409-0903-03 3.05 2.54
(12ML W/CANNULA)
0.9%, 5 ml. . 00409-6013-05 4.10 3.42
(12ML,PRE-FILLED SYRINGE)
0.9%, 5 ml. 00409-0905-05 3.30 2.75
(12ML W/CANNULA)
0.9%, 10 ml . . 00409-6014-10 4.50 3.75
(12ML,PRE-FILLED SYRINGE)
0.9%, 10 ml 00409-0906-10 3.70 3.08

SODIUM CHLORIDE/TETRASTARCH
(Hospira) *See VOLUVEN*

SODIUM CHLORIDE/TOBRAMYCIN SULFATE
(Hospira)
SOL, IV (PREMIX,24X100ML)
0.9%-80 mg/100 ml,
100 ml 24s . 00409-3470-23 263.52 230.64
(PREMIX,LATEX-FREE)
0.9%-60 mg/50 ml,
50 ml 24s 00409-3469-13 229.54 200.88

SODIUM CHROMATE
(Baker, J.T.) *See SODIUM CHROMATE TETRAHYDRATE*

SODIUM CHROMATE CR 51
(Bracco Diag) *See CHROMITOPE SODIUM*

(Mallinckrodt Inc.)
SOL, IV, 100 uci/ml
2.5 ml 00019-N370-25 676.80 564.00

SODIUM CHROMATE TETRAHYDRATE (Baker, J.T.)
sodium chromate
CRY, NA (REAGENT)
125 gm 10106-3840-04 55.26
500 gm 10106-3840-01 100.37

SODIUM CITRATE
(Baker, J.T.) *See SODIUM CITRATE DIHYDRATE*

(Citra) *See TRICITRASOL*

(Gallipot) *See SODIUM CITRATE DIHYDRATE*

(Humco)
GRA, NA (U.S.P.)
454 gm 00395-2691-81 12.59

(Mallinckrodt Lab) *See SODIUM CITRATE DIHYDRATE*

(Medisca) *See SODIUM CITRATE DIHYDRATE*

(PCCA)
POW, NA (USP, ANHYDROUS)
1 gm 51927-1144-00 0.09

(Spectrum Pharmacy) *See SODIUM CITRATE ANHYDROUS*

(Spectrum Pharmacy) *See SODIUM CITRATE DIHYDRATE*

SODIUM CITRATE ANHYDROUS (Spectrum Pharmacy)
sodium citrate
POW, NA (F.C.C.)
100 gm . 49452-6707-01 35.70
(U.S.P.)
100 gm . 49452-6711-01 32.73
(F.C.C.)
500 gm. . 49452-6707-02 49.88
(U.S.P.)
500 gm . 49452-6711-02 48.65
(F.C.C.)
2500 gm 49452-6707-03 187.25
(U.S.P.)
2500 gm. . . . 49452-6711-03 171.33

SODIUM CITRATE DIHYDRATE (Baker, J.T.)
sodium citrate
GRA, NA (U.S.P., F.C.C., A.C.S.)
500 gm. . 10105-3849-01 10.79
2500 gm . 10106-3849-05 .82.09
POW, NA (U.S.P., F.C.C.)
500 gm . 10105-3850-01 10.92
2500 gm 10106-3850-05 91.20

(Gallipot)
GRA, NA (U.S.P.,N.F.)
454 gm . 51552-0191-08 10.08
2270 gm 51552-0191-09 29.68

(Mallinckrodt Lab)
CRY, NA (U.S.P.)
500 gm . . 00406-0734-04 29.53
2500 gm . . 00406-0734-06 95.94

(Medisca)
POW, NA (U.S.P.)
100 gm . . . 38779-0543-05 22.50
500 gm . . . 38779-0543-08 34.50
(USP)
2500 gm 38779-0543-01 87.00

(Spectrum Pharmacy)
GRA, NA (U.S.P.)
500 gm. . 49452-6718-01 39.03
2500 gm. . . 49452-6718-02 115.33
12000 gm 49452-6718-03 511.00

SODIUM COBALTINITRITE (Baker, J.T.)
POW, NA (A.C.S., REAGENT)
125 gm 10106-3856-04 69.78
500 gm. 10106-3856-01 209.55

SODIUM CYANIDE (Baker, J.T.)
GRA, NA (A.C.S., REAGENT)
125 gm. 10106-3862-04 23.90
500 gm. 10106-3862-01 42.02

(Mallinckrodt Lab)
GRA, NA (A.C.S.)
500 gm 00406-7816-04 29.13

SODIUM DEHYDROACETATE (PCCA)
POW, NA, 1 gm . 51927-3581-00 0.41

SODIUM DESOXYCHOLATE
(PCCA) *See DEOXYCHOLIC ACID*

SODIUM DICHROMATE
(Baker, J.T.) *See SODIUM DICHROMATE DIHYDRATE*

SODIUM DICHROMATE DIHYDRATE (Baker, J.T.)
sodium dichromate
CRY, NA (A.C.S., REAGENT)
125 gm . . 10105-3872-04 77.35
500 gm 10106-3872-01 139.20

SODIUM DITHIONITE (Baker, J.T.)
POW, NA (PURIFIED)
500 gm 10106-3712-01 31.63
2500 gm 10106-3712-05 103.62

SODIUM EDECRIN (Aton)
ethacrynate sodium
PDS, IV, 50 mg, 1 . . . 25019-0210-27 162.69

SODIUM FERRIC GLUCONATE COMPLEX
(Watson) *See FERRLECIT*

SODIUM FLUORIDE (Amend)
POW, NA (U.S.P.)
125 gm. 17317-0588-04 8.40
500 gm. 17317-0588-01 19.60
2270 gm. 17317-0588-05 84.00

A-85

(Baker, J.T.)
POW, NA (U.S.P., A.C.S.)
500 gm 10106-3689-01 33.10
1 gm 10106-3689-05 284.89

(Oral) *See LURIDE*

(Colgate Oral) *See PHOS-FLUR*

(Colgate Oral) *See PREVIDENT*

(Colgate Oral) *See PREVIDENT 5000 BOOSTER*

(Colgate Oral) *See PREVIDENT 5000 PLUS*

(Colgate Oral) *See PREVIDENT DENTAL RINSE*

(Colgate Oral) *See THERA-FLUR-N*

(Consolidated Midland)
CTB, PO, 1 mg, 100s ea ... 00223-1773-01 2.50
1000s ea ... 00223-1773-02 15.75

(Contract Pharmacal)
CTB, PO (SF,GRAPE)
1.1 mg, 100s ea ... 10267-1640-01 4.90
1000s ea ... 10267-1640-04 54.10
(SF,CHERRY)
2.2 mg, 100s ea ... 10267-1641-01 5.10 EE
1000s ea ... 10267-1641-04 55.10 EE

(Cypress Pharm) *See FLUORIDE*

(Cypress Pharm) *See NEUTRAL SODIUM FLUORIDE*

(Cypress Pharm) *See SF 1.1% GEL*

(Cypress Pharm) *See SF 5000 PLUS*

(Dreir Pharmaceutical) *See LOZI-FLUR*

(Ethex) *See ETHEDENT*

(Fluoritab) *See FLUORITAB*

(Gallipot)
POW, NA, 113.4 gm (U.S.P.) ... 51552-0148-04 10.99
454 gm ... 51552-0148-08 28.91

(Hi-Tech)
LIQ, PO (SF,PEACH,DROPS)
0.5 mg/ml, 50 ml ... 50383-0656-50 8.05

(Imco)
GEL, DE, 1%, 60 gm ... 00802-3923-92 10.93

(Kirby Labs) *See FLURA-DROPS*

(Kirby Labs) *See FLURA-LOZ*

(Mallinckrodt Lab)
POW, NA (A.C.S.)
500 gm ... 00406-7636-04 81.55

(Medisca)
POW, NA (U.S.P.)
100 gm ... 38779-0094-05 25.50
500 gm ... 38779-0094-09 55.50
2500 gm ... 38779-0094-01 255.00

(Omnii Intl) *See CAVIRINSE*

(Omnii Intl) *See CONTROL RX*

(Oral B Lab) *See FLUORINSE*

(Pascal Co.) *See NEUTRAGARD ADVANCED*

(PCCA)
POW, NA (USP)
1 gm ... 51927-1038-00 0.48

(Perry Med)
CTB, PO (RASPBERRY)
0.25 mg, 100s ea ... 11763-0398-01 2.52
1000s ea ... 11763-0398-04 11.00
0.5 mg, 100s ea ... 11763-0217-01 2.31
1000s ea ... 11763-0217-04 11.00
(SF,GRAPE)
1 mg, 1000s ea ... 11763-0319-04 11.00
(SF,RASPBERRY)
1 mg, 1000s ea ... 11763-0317-04 11.00

(Perry Med) *See FLUORABON*

(Pharmascience Labs) *See FLUOR-A-DAY*

(Rising) *See DENTA 5000 PLUS*

(Rising) *See DENTAGEL*

(Spectrum Pharmacy)
POW, NA (U.S.P.)
125 gm ... 49452-6740-05 42.88
500 gm ... 49452-6740-01 94.50
2500 gm ... 49452-6740-02 416.50

(Unit)
... mg, 100s ea ... 54569-2878-01 5.54
IO, PO, ... mg/ml, 50 ml 54569-4557-00 7.00

(Dispensing Solutions)
REPACK
CTB, PO (SF,GRAPE)
1.1 mg, 90s ea ... 68336-6660-90 12.98
TAB, PO, 2.2 mg, 90s ea ... 68336-0263-90 8.01

(ORx)
REPACK
CTB, PO (SF,CHERRY)
2.2 mg, 100s ea ... 55045-3353-00 9.00 EE

(Palmetto)
REPACK
CTB, PO, 2.2 mg, 90s ea ... 23490-7879-01 8.19
100s ea ... 23490-7879-00 9.10

(PD-Rx Pharm)
REPACK
CTB, PO, 1 mg, 120s ea ... 55289-0676-98 7.89

(Phys Total Care)
REPACK
CTB, PO, 1 mg, 120s ea ... 54868-5169-00 21.45
LIQ, PO (DROPS)
0.125 mg/drp.
30 ml ... 54868-1941-00 13.68
(SF,PEACH,DROPS)
0.5 mg/ml, 50 ml ... 54868-1941-01 12.18

(Southwood)
REPACK
CTB, PO, 1 mg, 100s ea ... 58016-0977-00 4.84
LIQ, PO (DROPS)
0.125 mg/drp.
30 ml ... 58016-0977-01 7.70

SODIUM FORMALDEHYDE SULFOXYLATE (PCCA)
sodium formaldehydesulfoxylate
POW, NA, 1 gm ... 51927-3421-00 3.60

SODIUM FORMALDEHYDESULFOXYLATE
(PCCA) *See SODIUM FORMALDEHYDE SULFOXYLATE*

SODIUM FORMATE (Baker, J.T.)
CRY, NA (A.C.S., REAGENT)
500 gm ... 10106-3799-01 48.26
2500 gm ... 10106-3799-05 226.75
12000 gm ... 10106-3799-07 769.00

SODIUM GLUCONATE (Amend)
POW, NA (F.C.C.)
454 gm ... 17317-0901-01 8.40
2270 gm ... 17317-0901-05 33.60
11350 gm ... 17317-0901-08 105.00

(PCCA)
POW, NA (USP)
1 gm ... 51927-2377-00 0.10

(Spectrum Pharmacy)
POW, NA (U.S.P.)
500 gm ... 49452-6745-01 46.20
2500 gm ... 49452-6745-02 177.63
12000 gm ... 49452-6745-03 539.00

SODIUM GLYCEROPHOSPHATE (Amend)
POW, NA (N.F.)
125 gm ... 17317-0510-04 18.20
454 gm ... 17317-0510-01 44.80
2270 gm ... 17317-0510-05 198.00

SODIUM HEXAMETAPHOSPHATE (Amend)
sodium polymetaphosphate
POW, NA (FOOD GRADE)
454 gm ... 17317-1547-01 8.40
2270 gm ... 17317-1547-05 29.40
11350 gm ... 17317-1547-08 82.50

(Spectrum Pharmacy)
GRA, NA (F.C.C.)
500 gm ... 49452-6770-01 53.03
2500 gm ... 49452-6770-02 122.85

SODIUM HYALURONATE (Cypress Pharm)
hyaluronate sodium
GEL, TP (1X340GM)
0.2%, 340 gm ... 68258-0026-12 101.12

SODIUM HYALURONATE 0.1% HYDRATING LOTION
(Hi-Tech)
hyaluronate sodium
LOT, TP (1X340GM)
0.1%, 340 gm ... 50383-0283-12 78.65
(1X1000GM)
0.1%, 1000 gm ... 50383-0293-36 140.47

SODIUM HYALURONATE HYDRATING LOTION
(Cypress Pharm)
hyaluronate sodium
LOT, TP (1X1000GM,VISCOELASTIC)
0.1%, 1000 gm ... 68258-0025-10 140.47

SODIUM HYDROXIDE (Amend)
PEL, NA (A.C.S., REAGENT)
500 gm ... 17317-1357-01 11.20
2500 gm ... 17317-1357-05 38.50
POW, NA (N.F., F.C.C.)
454 gm ... 17317-0511-01 7.00
2270 gm ... 17317-0511-05 23.10
11350 gm ... 17317-0511-08 52.75

(Baker, J.T.)
FLA, NA (PURIFIED)
500 gm ... 10106-3734-01 34.25
2500 gm ... 10106-3734-05 88.84
PEL, NA (F.C.C., N.F.)
125 gm ... 10106-3728-04 25.88
500 gm ... 10106-3728-01 20.85

(Baker, J.T.) *See SODIUM HYDROXIDE 10N*

(Baker, J.T.) *See SODIUM HYDROXIDE 25%*

(Baker, J.T.) *See SODIUM HYDROXIDE 50%*

(Baker, J.T.) *See SODIUM HYDROXIDE 6N*

(Gallipot)
FLA, NA (TECHNICAL)
22700 gm ... 51552-0624-09 93.80
PEL, NA (U.S.P.,N.F.)
454 gm ... 51552-0080-06 14.42

(Gallipot) *See SODIUM HYDROXIDE 0.1N*

(Gallipot) *See SODIUM HYDROXIDE 10%*

(Gallipot) *See SODIUM HYDROXIDE 20%*

(Gordon) *See SODIUM HYDROXIDE 10%*

(Letco)
PEL, NA (N.F.)
500 gm ... 62991-2061-01 32.25
2500 gm ... 62991-2061-02 75.00

(Mallinckrodt Lab)
PEL, NA (N.F.)
500 gm ... 00406-7660-04 29.26

(PCCA)
POW, NA (NF (CAUSTIC SODA))
1 gm ... 51927-1237-00 0.09

(Spectrum Pharmacy)
PEL, NA (N.F.)
500 gm ... 49452-6780-01 48.30
2500 gm ... 49452-6780-02 122.33
12000 gm ... 49452-6780-03 427.00

SODIUM HYDROXIDE 0.1N (Gallipot)
sodium hydroxide
SOL, NA, 473 ml ... 51552-0558-06 8.40

SODIUM HYDROXIDE 10% (Gallipot)
sodium hydroxide
SOL, NA, 473 ml ... 51552-0406-06 14.49

(Gordon)
SOL, NA, 60 ml ... 10481-3086-01 32.50

SODIUM HYDROXIDE 10N (Baker, J.T.)
sodium hydroxide
SOL, NA (REAGENT, VOLUMETRIC)
1000 ml ... 10106-5874-02 30.39
4000 ml ... 10106-5874-03 52.32
4000 ml ... 10106-5874-08 52.32
20000 ml ... 10106-5874-07 128.75

SODIUM HYDROXIDE 20% (Gallipot)
sodium hydroxide
SOL, NA (W/V)
473 ml ... 51552-0510-06 14.70

SODIUM HYDROXIDE 25% (Baker, J.T.)
sodium hydroxide
SOL, NA (REAGENT)
1000 ml ... 10106-5861-02 39.86
4000 ml ... 10106-5861-03 66.60
20000 ml ... 10106-5861-07 202.34

SODIUM HYDROXIDE 50% (Baker, J.T.)
sodium hydroxide
SOL, NA (REAGENT)
500 ml ... 10106-3727-01 46.66
4000 ml ... 10106-3727-03 103.67
19000 ml ... 10106-3727-07 280.06

SODIUM HYDROXIDE 6N (Baker, J.T.)
sodium hydroxide
SOL, NA (REAGENT, VOLUMETRIC)
1000 ml ... 10106-5872-02 28.63
4000 ml ... 10106-5872-03 44.29
20000 ml ... 10106-5872-07 105.94

SODIUM HYPOCHLORITE
(Baker, J.T.) *See SODIUM HYPOCHLORITE 5%*

A86

Helen Stubbert

86224-9

From: OFFICE RECEPTIONIST, CLERK [SUPREME@COURTS.WA.GOV]
Sent: Monday, December 19, 2011 2:30 PM
To: Helen Stubbert
Cc: geraldsteel@yahoo.com
Subject: RE: Protect the Peninsula's Future; et al. v. City of Port Angeles; et al., Supreme Court #86224-9

We have accepted the brief for filing but the appendix is to large to send via email. Please mail the appendix with a cover letter.
Thank you. Here is a link on our website that they cannot be larger than 25 pages.
http://www.courts.wa.gov/appellate_trial_courts/supreme/clerks/?fa=atc_supreme_clerks.display&fileID=fax

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From: Helen Stubbert [mailto:stubh@foster.com]
Sent: Monday, December 19, 2011 2:25 PM
To: OFFICE RECEPTIONIST, CLERK
Cc: geraldsteel@yahoo.com
Subject: Protect the Peninsula's Future; et al. v. City of Port Angeles; et al., Supreme Court #86224-9

Attached for filing are: (1) Brief of Respondents, and (2) Declaration of Service.
Hard copies are being mailed today to Mr. Steel.

Helen Stubbert
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Steven J. Gillespie
Russell D. Terry
Foster Pepper PLLC
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